



HeartWare[®] Ventricular Assist System

Instructions for Use

Caution: Federal law restricts this device to sale by or on the order of a physician.

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FOREWORD

The HeartWare® Ventricular Assist System is indicated for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. Clinical users include physicians, registered nurses, perfusionists and biomedical engineers. Implant of the device must be performed by a qualified cardiac surgeon trained by HeartWare-authorized personnel. Clinical users of the HeartWare® System should attend HeartWare clinical operator training, should have a working knowledge of the principles of left ventricular assist devices (LVADs), and should be aware of the physical and psychological needs of patients undergoing LVAD support. Patients and caregivers should complete a user training program and demonstrate their ability to use the system. Clinicians should read the entire Instructions for Use before system operation. This manual may serve as a reference for detailed information including specific information on device function, system setup, implant and maintenance. This manual is not intended to replace comprehensive educational programs or to supersede acquired knowledge or proper medical judgment.

WARNING! Carefully read this entire manual prior to implanting or operating the device.
Improper operation of the system and potential harm to the patient and to the user could result.

1.0 INTRODUCTION

STERILE: All HeartWare components used at implant including surgical tools are provided sterile.

The HeartWare® Ventricular Assist System (HeartWare® System) is designed to assist a weakened, poorly functioning left ventricle. The HeartWare® System utilizes a centrifugal blood pump, the HVAD® Pump (the "pump"), which is implanted in the pericardial space with left ventricular apex to ascending aortic cannulation for left ventricular support (Figure 1). The inflow conduit, which is partially sintered, is integrated with the pump and a 10mm gel impregnated outflow graft with a strain relief is attached to the pump. A percutaneous driveline connects the pump to an external controller. The controller, powered by two batteries or by one battery and electricity from the wall or car outlet, regulates pump function and monitors the system. The monitor is used to display system performance and to change controller operating parameters. A battery charger is also included.

All components of the HeartWare® System are designed to be used only in conjunction with each other. They are neither compatible nor intended to be used with other manufacturer's devices.

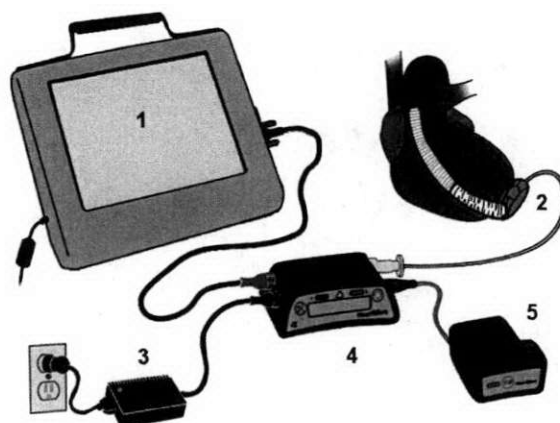


Figure 1: HeartWare® Ventricular Assist System

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|---------------|---------------|
| 1. Monitor | 4. Controller |
| 2. HVAD® Pump | 5. Battery |
| 3. AC Adapter | |

2.0 INDICATIONS FOR USE

The HeartWare® Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HeartWare® System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.

3.0 CONTRAINDICATIONS

The HeartWare® System is contraindicated in patients who cannot tolerate anticoagulation therapy.

4.0 WARNINGS

1. **WARNING!** Serious and life threatening adverse events, including stroke, have been associated with use of this device. A user must fully consider the risks of this device with that of other treatment modalities before deciding to proceed with device implantation. Please see Section 6.4 for a summary of the stroke data. To mitigate the risk of stroke, please adhere to the following patient management guidelines:
 - Maintain MAP at <85 mm Hg as tolerated. The HVAD® Pump is sensitive to both preload and afterload.
 - Ramp speed and flows more slowly during the first few weeks (e.g. 30 days) post-implant to avoid excessive hemodynamic forces that may damage fragile blood vessels that have undergone remodeling secondary to the lower pressures and reduced flow associated with medically-treated heart failure. There is no apparent need to exceed a cardiac index of 2.6 L/min/m² until patients have fully recovered from the implant surgery and physical performance improves. A cardiac index of 2.6 L/min/m² is the lower limit of normal for a healthy adult.
 - Maintain anticoagulation within the recommended INR range of 2.0-3.0.
 - Check for ASA resistance with a reliable test (e.g. VerifyNow®) and adjust ASA mono-therapy accordingly or consider combination therapy such as ASA 81 mg plus Aggrenox® (ASA plus extended-release dipyridamole) or daily ASA 81 mg plus Plavix 75 mg. In general, mono-therapy with ASA is not encouraged in the absence of testing for resistance.
2. **WARNING!** Do not use the HeartWare System in pregnant women. Any woman receiving a HeartWare System who is of childbearing age and sexually active should use a reliable method of birth control. Use of anticoagulants during pregnancy has been associated with birth defects and bleeding.
3. **WARNING!** The Instructions for Use (IFU) is intended to be used by physicians, nurses, and other clinical professionals. Setup and operation of this device should only be undertaken by personnel who have completed a HeartWare product training program. A thorough understanding of technical principles, clinical applications and risks associated with the HeartWare® System is required before using this product. Failure to understand these principles, applications and risks may result in improper operation of the system and potential harm to the patient or to the user.
4. **WARNING!** Carefully read this entire manual prior to implanting or operating the device. Improper operation of the system and potential harm to the patient and to the user could result.
5. **WARNING!** NEVER disconnect both power sources (batteries and AC or DC adapter) at the same time since this will stop the pump. At least one power source must be connected at all times.

6. **WARNING!** DO NOT rely only on flow estimation to assess cardiac output. An average estimated flow on the monitor or controller display of less than 2 L/min, or greater than 10 L/min may indicate an electrical fault, incorrect hematocrit entry or an occlusion due to thrombus or other materials (e.g. tissue fragments) in the device. Inaccurate assessment of HVAD® Pump flow may lead to less than optimal treatment.
7. **WARNING!** ALWAYS investigate, and if possible, correct the cause of any alarm. Silencing an alarm does not resolve the alarm condition.
8. **WARNING!** DO NOT grasp the driveline cable as this may damage the driveline. To remove the driveline from the controller, first pull back the driveline cover then grasp and pull the driveline connector.
9. **WARNING!** DO NOT disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.
10. **WARNING!** DO NOT operate the controller in temperatures less than -20°C (-4°F) or greater than 50°C (122°F) or the controller may fail.
11. **WARNING!** DO NOT attach the alarm adapter to a controller connected to the running pump. The alarm adapter silences the "No Power" alarm and should only be attached to a controller that has failed or malfunctioned and is no longer connected to a pump.
12. **WARNING!** ALWAYS keep a spare controller and fully charged spare batteries available at all times in case of an emergency.
13. **WARNING!** DO NOT plug the AC adapter into an electrical outlet which is not properly grounded or you may receive a serious electrical shock.
14. **WARNING!** ALWAYS check the controller display for any information regarding an alarm when using loud machinery or in the vicinity of loud noises as the alarms may not be audible.
15. **WARNING!** ALWAYS replace a controller with a blank display or no audible alarms. This condition is predictive of a controller failure.
16. **WARNING!** ALWAYS switch to the backup controller if there is a "Controller Failed" alarm since the HVAD® Pump may not be running.
17. **WARNING!** The HVAD® Pump may cause interference with AICDs. If electromagnetic interference occurs, it may lead to inappropriate shocks, arrhythmia and possibly death. The occurrence of electromagnetic interference with AICD sensing may require adjustment of lead sensitivity, proximal placement of new leads or replacement of an existing sensing lead.
18. **WARNING!** Keep both power supplies connected to the controller after setting up the primary controller to minimize the risk of air embolus during implant. Disconnecting and then reconnecting both power supplies will result in the controller starting the pump as soon as the driveline is connected.
19. **WARNING!** DO NOT use if package is damaged or opened. Sterile components are intended for single use only. DO NOT re-sterilize or re-use as this will increase the risk of infection.
20. **WARNING!** ALWAYS check for an audible click when connecting the driveline to the controller or driveline extension cable. Failure to ensure a secure connection may cause an electrical fault.
21. **WARNING!** NEVER turn on the HVAD® Pump in air as this may damage the pump. DO NOT use an HVAD® Pump that was turned on without total submersion in fluid during the pre-implant test and prior to implantation: The HVAD® Pump must be completely submerged in fluid before being turned on.

22. **WARNING!** DO NOT implant gel impregnated vascular prostheses in patients who exhibit sensitivity to polyester or materials of bovine origin, as severe reactions may occur.
 23. **WARNING!** DO NOT allow the Gelweave prostheses non-sterile foil pouch or outer tray to be introduced to the sterile field or the sterile field will be contaminated. Only the innermost tray is sterile.
 24. **WARNING!** DO NOT preclot the outflow graft. Preclotting may disrupt the gel matrix, resulting in bleeding. Gelweave prostheses are sealed grafts and must not be preclotted.
 25. **WARNING!** DO NOT implant the Gelweave prostheses more than one month after removal from the foil pouch. This may disrupt the gel matrix, resulting in bleeding.
 26. **WARNING!** DO NOT allow anyone but a surgeon, physician's assistant or surgical assistant trained in the procedure to attach the outflow graft to the pump, as a loose graft connection may lead to bleeding and/or an air embolus.
 27. **WARNING!** ALWAYS rotate the strain relief so that the clamp screw is located on the inner side of the outflow conduit to avoid tissue irritation or damage.
 28. **WARNING!** DO NOT use excessive force when tightening the clamp screw because this could damage the graft clamp or graft clamp screw and a loose connection may result in bleeding and/or an air embolus. Replace components if required.
 29. **WARNING!** DO NOT over-loosen the sewing ring's screw or it may fall off the sewing ring and be lost in the sterile field.
 30. **WARNING!** DO NOT cut the outflow graft too short or too long, or it may kink. Prior to chest closure, ensure that the graft is not kinked or compressed. A kinked or compressed outflow graft may lead to reduced flow and/or thrombus formation.
 31. **WARNING!** DO NOT immerse the Gelweave grafts in saline for longer than 5 minutes. Longer periods of soaking in saline may disrupt the gel matrix, resulting in bleeding.
 32. **WARNING!** ALWAYS position the driveline exit site so that the tunneler does not contact any vital organs or structures.
 33. **WARNING!** DO NOT grasp the driveline and pull as this may damage the driveline. To remove the driveline cap from the driveline, unscrew the outer sleeve, then pull back on the grooved part of the connector.
 34. **WARNING!** ALWAYS remove all air from the HVAD® Pump and its conduits to reduce risk of air embolus.
 35. **WARNING!** DO NOT de-air the HVAD® Pump when there is inadequate blood volume in the HVAD® Pump or leaks in the inflow/outflow connections, as air may enter the HVAD® Pump and outflow graft resulting in a delay in de-airing and possible air embolism.
 36. **WARNING!** DO NOT allow patients to shower until they have received permission from their clinician to do so. Patients who shower must use the HeartWare® Shower Bag.
 37. **WARNING!** DO NOT allow hearing impaired patients to shower unless their caregiver is close by to hear alarms.
 38. **WARNING!** DO NOT plug the controller into an AC wall outlet during showers; to eliminate the possibility of a severe electrical shock, it should be connected to two batteries.
 39. **WARNING!** DO NOT allow patients to take a bath or swim, as this may damage HeartWare® System components and/or result in driveline exit site infection.
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40. **WARNING!** DO NOT submerge HeartWare® System components in water or other fluid as this may damage them. If this happens, contact HeartWare.
41. **WARNING!** DO NOT allow water or other fluids to enter the controller, power adapters, batteries, battery charger or connectors, as this may damage HeartWare® System components. If this happens, contact HeartWare.
42. **WARNING!** AVOID areas with high magnetic forces such as theft detection devices or airport security systems, as this may affect HeartWare® System operation.
43. **WARNING!** Keep mobile phones at least 20 inches (50 centimeters) away from the controller, as mobile phones may interfere with controller operation.
44. **WARNING!** DO NOT let the patient have a *magnetic resonance imaging (MRI) procedure* while implanted with the HVAD® Pump. Doing so could cause harm to the patient or could cause the pump to stop.
45. **WARNING!** DO NOT apply high power electrical treatment (e.g. application of diathermy) directly to the patient, as this may affect HeartWare® System operation.
46. **WARNING!** AVOID therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm.
47. **WARNING!** AVOID therapeutic ionizing radiation since it may damage the device. This damage may not be immediately detectable.
48. **WARNING!** DO NOT use any components other than those supplied by HeartWare with the HeartWare® System, as this may affect HeartWare® System operation.
49. **WARNING!** DO NOT drop the controller or other equipment. Dropping the controller could cause sudden stoppage of the pump. Dropped equipment should be reported to HeartWare and inspected.
50. **WARNING!** Damaged equipment should be reported to HeartWare and inspected.
51. **WARNING!** NEVER clean the battery charger with the power on, as this may lead to an electrical shock.
52. **WARNING!** NEVER clean the monitor with the power on, as this may lead to an electrical shock. DO NOT use alcohol or detergent on the monitor display. Gently wipe the display with a soft, lint free cloth.
53. **WARNING!** DO NOT disconnect the driveline or power sources from the controller while cleaning it or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

5.0 PRECAUTIONS

1. **CAUTION:** Safety and effectiveness in persons less than 18 years of age and in persons with a BSA of less than 1.5 m² have not been established.
2. **CAUTION:** The HeartWare® Ventricular Assist System has had limited use in patients with artificial mitral or aortic valves and therefore the risks are currently unknown. Caution should be used in selecting patients with artificial mitral or aortic valves for HeartWare® System therapy.
3. **CAUTION:** ONLY use HeartWare® Controllers on one patient to avoid risks associated with an inadvertent mismatch of controller pump speed settings.

4. **CAUTION:** Manual changes to the speed will immediately disable the ventricular suction detection alarm. An "Sx Off" will be displayed on the monitor screen below the "Fixed" mode display. The ventricular suction detection alarm will have to be re-activated.
5. **CAUTION:** DO NOT enable the ventricular suction detection alarm while the patient is in a suction condition. To optimize operation of the suction detection the patient should be hemodynamically stable prior to enabling the ventricular suction detection alarm.
6. **CAUTION:** ALWAYS fully charge the monitor's internal battery prior to patient use.
7. **CAUTION:** DO NOT allow patients to touch the monitor, as this may lead to the entering of unwanted HeartWare® System parameters.
8. **CAUTION:** DO NOT use the "Set Defaults" button on the monitor when a controller is connected to a patient. Pressing it will erase all patient VAD parameter information from the controller.
9. **CAUTION:** ALWAYS recharge fully depleted batteries within 24 hours to avoid permanent battery damage.
10. **CAUTION:** DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.
11. **CAUTION:** ALWAYS confirm that the power cables are properly locked on the controller by gently *pulling the cable near the controller power connector* or the power cables may come loose and result in an alarm or the pump stopping.
12. **CAUTION:** DO NOT expose batteries to temperatures outside the storage and operational ranges or they may provide less support than usual. To preserve battery life, batteries should be stored at room temperature.

Battery operating and storage temperatures:

- a. Operating: discharge (normal use with the HeartWare® System) and charge (while on battery charger): 0°C to 45°C (+32°F to 113°F). Operation at temperatures below 0°C will **temporarily** reduce battery capacity but the battery will operate.
 - b. Storage: -20°C to 25°C (-4°F to 77°F). Long term storage outside of this range may **permanently** reduce the battery capacity. Best condition for storage is at room temperature.
13. **CAUTION:** ALWAYS keep batteries away from children. Children may be harmed by damaged batteries or components.
 14. **CAUTION:** DO NOT disassemble, crush, or puncture a battery.
 15. **CAUTION:** DO NOT use a damaged battery. Battery function is unknown if the battery is damaged.
 16. **CAUTION:** DO NOT short circuit the external contacts on a battery since this may result in battery damage.
 17. **CAUTION:** DO NOT touch the fluid if a battery pack is leaking fluid. Dispose of a leaking battery pack. In case of eye contact with fluid, DO NOT rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention.
 18. **CAUTION:** DO NOT expose batteries to excessive shock or vibration since this may affect battery operation.
 19. **CAUTION:** DO NOT dispose of a battery in fire or water. Dispose of batteries according to federal, state, and local regulations.

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20. **CAUTION:** ONLY use the HeartWare® Battery Charger to charge HeartWare® Batteries. Other battery chargers will not charge the batteries and may damage them.
 21. **CAUTION:** ALWAYS wait until the "Ready" light turns on to disconnect the battery from the battery charger. If this is not followed over consecutive charging cycles, the Battery Capacity Display will not function properly and may convey misleading battery capacity.
 22. **CAUTION:** DO NOT use HeartWare equipment in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
 23. **CAUTION:** A backup controller should always be available and programmed identically to the primary controller.
 24. **CAUTION:** DO NOT exert excessive tension or force on the Gelweave prostheses as it will damage the polyester fibers and the gelatin impregnation, which may result in bleeding.
 25. **CAUTION:** ALWAYS ensure the inflow cannula position is pointed toward the mitral valve and parallel to the interventricular septum to optimize HVAD® Pump operation.
 26. **CAUTION:** ALWAYS position the sewing ring to permit access to its screw after cannulation.
 27. **CAUTION:** ALWAYS use round body taper point needles when implanting Gelweave prostheses to minimize fiber damage. A kinked or compressed outflow graft may lead to reduced flow and/or thrombus formation.
 28. **CAUTION:** The driveline connector is made of nickel-coated brass which may cause a rash in patients with a nickel allergy.
 29. **CAUTION:** ALWAYS be aware of the position of the driveline to avoid damage by surgical instruments and needles during HVAD® Pump implantation and/or re-operation.
 30. **CAUTION:** ALWAYS use the smallest possible needle for de-airing; 19-gauge is normally sufficient. Hypodermic needles have a cutting point which may result in blood leakage and may require repair by suturing.
 31. **CAUTION:** DO NOT rely on HVAD® Pump flow estimation during the de-airing procedure. Flow estimation may not be accurate.
 32. **CAUTION:** Chest compressions may pose a risk due to pump location and position of the outflow graft on the aorta - use clinical judgment. If chest compressions have been administered, confirm function and positioning of HVAD® Pump.
 33. **CAUTION:** ALWAYS examine the driveline for evidence of tears, punctures or breakdown of any of the material during exit site dressing changes. Driveline damage may affect HeartWare® System performance.
 34. **CAUTION:** AVOID the use of prophylactic topical antibiotic ointments such as silver sulfadiazine, betadine or polymyxin-neomycin-bacitracin on the tissue around the driveline exit site as these ointments can injure the tissue.
 35. **CAUTION:** DO NOT pull, kink or twist the driveline or the power cables, as these may damage the driveline. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting controller or power sources, or when using the shower bag.
 36. **CAUTION:** ALWAYS keep all connectors free of liquid, dust and dirt, or the HeartWare® System may not function as intended.
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37. **CAUTION:** DO NOT attempt to repair or service any components of the HeartWare® System. If HeartWare® System equipment malfunctions, contact HeartWare.
38. **CAUTION:** DO NOT place batteries in water or liquid.

6.0 POTENTIAL COMPLICATIONS

Implantation of a Ventricular Assist Device (VAD) is an invasive procedure requiring general anesthesia, a median sternotomy, a ventilator and cardiopulmonary bypass. These surgical procedures are associated with numerous risks. Adverse events that may be associated with the use of the HeartWare® System are listed below. Other than death, the adverse events are listed in alphabetical order.

- | | | |
|------------------------------------|---|------------------------------|
| • Death | • Hemolysis | • Peripheral thromboembolism |
| • Air embolism | • Hepatic dysfunction | • Platelet dysfunction |
| • Aortic insufficiency | • Hypertension | • Psychiatric episodes |
| • Bleeding, perioperative or late | • Interference with/from other devices | • Renal dysfunction |
| • Cardiac arrhythmias | • Local infection | • Re-operation |
| • Death | • Multi-organ failure | • Respiratory dysfunction |
| • Device malfunction | • Myocardial infarction | • Right ventricular failure |
| • Device thrombosis | • Neurologic dysfunction | • Sensitivity to aspirin |
| • Driveline infection | • Organ damage during driveline tunneling | • Sepsis |
| • Driveline perforation | • Pericardial effusion/tamponade | • Stroke |
| • Driveline wire damage | | • Worsening heart failure |
| • Erosions and other tissue damage | | • Wound dehiscence |
| • GI bleeding/ AV malformations | | |

7.0 CLINICAL TRIAL RESULTS

7.1 Pivotal Clinical Study Design

This was a multi-center, prospective, contemporaneous control trial. The trial was non-randomized and open label. Enrollment in the study is complete, subjects have all reached the primary endpoint as described and specified in the protocol, but follow-up of subjects is ongoing.

Subjects were consented for participation and then assessed against the inclusion and exclusion criteria for participation in the study and implantation of the HVAD® Pump. After the surgical recovery period, patients were allowed to leave the hospital if they met additional criteria for hospital discharge. Each patient was followed to 180 days, death, device explant for recovery, or cardiac transplantation, whichever occurred first.

Patient outcomes were compared to a contemporaneously treated cohort of patients as recorded in the Interagency Registry for Mechanical Assisted Circulatory Support (INTERMACS). All patients enrolled in the INTERMACS registry over the same enrollment period as the trial that met the control group inclusion and exclusion criteria comprised the control group.

7.2 Study Objectives

Primary Objective

The purpose of the HeartWare® Ventricular Assist System study was to evaluate the safety and effectiveness of the HeartWare® System in patients listed for cardiac transplantation with refractory, advanced heart failure at risk of death. The primary endpoint is success at 180 days which was defined as alive on the originally implanted device or transplanted or explanted for recovery. If explanted for recovery patients must have survived 60 days post-explant to be considered successful.

Effectiveness was measured by the primary endpoint. The proportion of study patients alive, transplanted, or explanted for recovery at 180 days was compared to the same proportion obtained from the INTERMACS registry cohort and tested for non-inferiority.

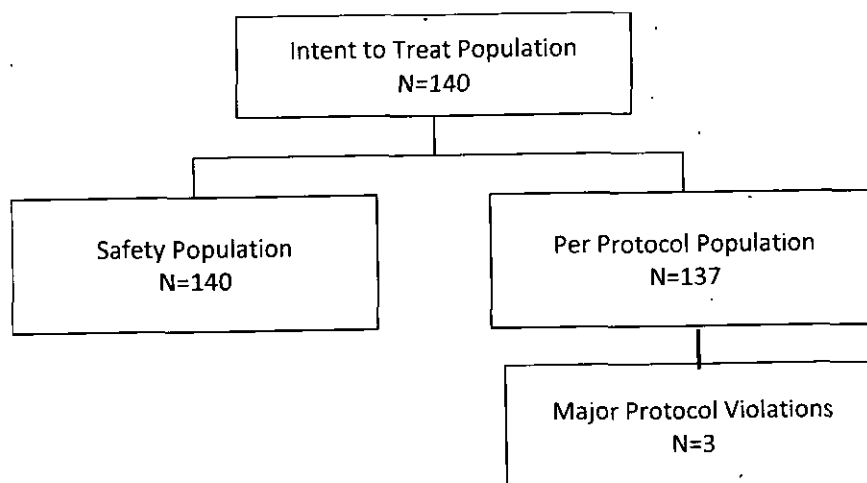
Secondary Objectives Including Safety

Secondary endpoints included: overall survival; incidence of all serious adverse events, including neurocognitive status and unanticipated adverse device effects; incidence of all device failures and device malfunctions; Quality of Life improvement, as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ) and European Quality of Life Assessment (EuroQoL) EQ-5D; and functional status improvement, as measured by New York Heart Association (NYHA) classification and 6-minute walk.

Safety measures included the frequency and rates of adverse events, overall and for each specific event, which were collected throughout HeartWare® System support.

7.3 Study Population Demographics and Baseline Parameters

There were three analysis populations defined for this trial. These are the intent-to-treat population (ITT), the Safety population (SAF) and the Per Protocol population (PP).



Subjects were predominately male (72.1%) and 53.3 ± 10.3 years of age. BSA and BMI were 2.1 ± 0.3 kg/m² and 28.6 ± 6.1 m², respectively. The principal etiology of heart failure was ischemic heart disease (41%) and the average LVEF was 17.8 ± 7.1 %. Pulmonary Capillary Wedge Pressure (PCWP) was elevated at 23 ± 9 mm Hg and pulmonary artery pressures were also high: $(49 \pm 15)/(25 \pm 9)$ mmHg. The majority of patients were classified as NYHA IV (95%). Laboratory values at baseline were, in general, unremarkable except for an elevated BUN (26 ± 14 mg/dL) and a depressed hematocrit (34 ± 5.8 %).

Eighty percent of subjects in the HeartWare® System treatment group were on inotropic therapy at baseline. Some (23%) were on more than one inotrope. IABP therapy at baseline was reported for 25% of subjects and 85% presented with an AICD. Subjects received typical medications for congestive heart failure with diuretics (82%) most common.

Comparison of Selected Baseline Characteristics between Treatment and Control Groups

The mean age of implant recipients in the HeartWare® System group was 53.3 (range 22-70) and for the control, 52.2. Other parameters available to compare included gender, BSA, BUN, right atrial pressure and creatinine. In all cases, the values for both the HeartWare treatment and control groups were not statistically significantly different (Table 1).

Table 1: Select Baseline Characteristics for HeartWare and INTERMACS Groups

| Characteristics | HeartWare® System N=140 | INTERMACS N=499 | p-value |
|------------------------------|----------------------------|--------------------|---------|
| Age (years) | 53.3 ± 10.3 | 52.2 ± 12.2 | 0.19 |
| Female Gender, n (%) | 39 (28%) | 120 (24%) | 0.36 |
| BSA (m ²) | 2.06 ± 0.28 | 2.07 ± 0.30 | 0.59 |
| BUN (mg/deciliter) | 25.3 ± 13.5 | 28.9 ± 20.9 | 0.94 |
| Right atrial pressure (mmHg) | 10.8 ± 3.3 | 11.5 ± 5.0 | 0.53 |
| Serum creatinine (mg/dL) | 1.3 ± 0.4 | 1.4 ± 0.6 | 0.89 |

7.4 Safety and Effectiveness Results

EFFECTIVENESS RESULTS

Primary Endpoint

The analysis of the primary endpoint demonstrated HVAD® non-inferiority to the control group (Table 2). The difference in success rates between the HVAD® group and controls was less than the 15% non-inferiority margin ($p < 0.0001$). The 95% one-sided UCL on the difference in success rates was 4.5% for the Safety (SAF) population analysis and 0.9% for the Per Protocol (PP) population analysis. *The pre-specified primary endpoint was achieved.*

Table 2: Success Rates and Inference on non-Inferiority

| | Implanted (N) | Successes N (%) | UCL (%) | p-value |
|---------------------|------------------|--------------------|---------|---------|
| Safety Cohort | | | | |
| HVAD® | 140 | 127 (90.7) | 4.5 | <0.0001 |
| Controls | 497 | 448 (90.1) | | |
| Per Protocol Cohort | | | | |
| HVAD® | 137 | 126 (92.0) | 0.9 | <0.0001 |
| Controls | 497 | 448 (90.1) | | |

P-value: From significance test of non-inferiority

UCL: 95% one-sided upper confidence limit on the difference in success rates

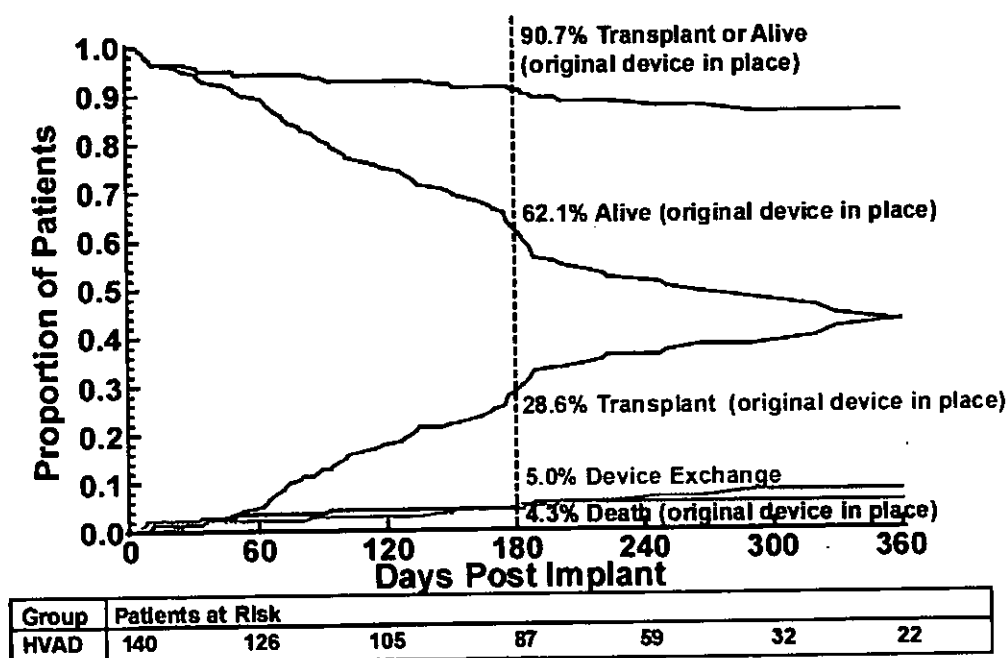
Note: The table accounts for 497 of the 499 INTERMACS patients; the remaining 2 patients, who withdrew consent before 180 days, have a missing success/failure outcome.

Competing Outcomes

A competing risks analysis was performed (Figure 2), estimating the time-related probability of experiencing each of the component events. These data are calculated from all events occurring during the study duration, including deaths, transplants and exchanges occurring after 180 days but ending with last-patient, last-visit.

Figure 2: Competing Risk Outcomes (HVAD® Safety Population)

HVAD patients (Safety Population): N = 140



Deaths

There were eight subject deaths during the 180-day study period. Six deaths occurred in subjects with their originally implanted device and two deaths occurred after device exchange.

Safety Results

This study was not randomized and used a contemporaneous control for the sole purpose of comparing a pre-defined success outcome. The adverse events reported here are unique to the HeartWare® System and have no randomized comparator arm.

Exposure

The total support (exposure) on the original HeartWare® System was 20,698 days or 56.7 patient-years. The mean duration on device for the 140 subjects was 147.8 days (standard deviation 52.8) with a median 180 (range 6 – 180 days). The mean duration on study was 222.5 days (standard deviation 119) with a median of 196 (range 11 – 588 days). Duration on study exceeds duration on device, because the follow-up post-transplant is included.

Adverse Events

A total of 776 events (Table 3) were reported by investigators during the 180 day period on the original device. Of these 437 (437/776, 56.3%) were INTERMACS defined specific events, and 338/776 (43.6%) events were recorded under the INTERMACS category of "Other." One UADE was reported during the 180-day primary endpoint period.

Table 3: Summary of All Investigator-Reported Adverse Events

| Event | Total | % |
|--------------------------|------------|-------------|
| INTERMACS defined Events | 437 | 56.3% |
| INTERMACS "Other" AE's | 338 | 43.6% |
| UADE | 1 | 0.1% |
| Total | 776 | 100% |

INTERMACS Events

The INTERMACS defined adverse events for the 180-day primary endpoint on original device are summarized below and are separated into the perioperative (0-30 days) and post-perioperative (31-180 days) periods. Events meeting INTERMACS criteria are shown in Table 4 below. Bleeding, infections and arrhythmia were the most common. Most bleeding events qualified due to transfusions (see definition below). On the other hand, all reoperations due to bleeding were in the first 30-days post-op (23 vs. 0 events post-30 days).

Table 4: INTERMACS Events by Type and Time of Onset
(HeartWare® System N=140)

| INTERMACS defined AEs | Day of Event Onset | | | |
|---|--------------------|-------------------|-------------|-------------------|
| | 0-30 Days | | 31-180 Days | |
| | Events N | Subjects N (%) | Events N | Subjects N (%) |
| BLEEDING | | | | |
| Re op ¹ | 23 | 20 (14.3) | 0 | 0 |
| Transfusion criteria ² >4 units within 7 days | 10 | 10 (7.1) | 0 | 0 |
| Any units at ≥7 days | 31 | 25 (17.9) | 46 | 20 (14.3) |
| Infections | | | | |
| Local (non-device) | 20 | 20 (14.3) | 17 | 17 (12.1) |
| Driveline exit | 5 | 5 (3.6) | 14 | 11 (7.9) |
| Sepsis ³ | 3 | 3 (2.1) | 8 | 7 (5.0) |
| Neurological Events | | | | |
| Ischemic CVA | 7 | 7 (5.0) | 3 | 3 (2.1) |
| Hemorrhagic CVA | 2 | 2 (1.4) | 2 | 2 (1.4) |
| TIA | 2 | 2 (1.4) | 5 | 4 (2.9) |
| Respiratory Dysfunction | 26 | 22 (15.7) | 8 | 5 (3.6) |
| Arrhythmia | | | | |

| INTERMACS defined AEs | Day of Event Onset | | | |
|------------------------------------|--------------------|-------------------|-------------|-------------------|
| | 0-30 Days | | 31-180 Days | |
| | Events N | Subjects N (%) | Events N | Subjects N (%) |
| Ventricular | 15 | 14 (10.0) | 14 | 11 (7.9) |
| Supraventricular | 25 | 21 (15.0) | 7 | 6 (4.3) |
| Right Heart Failure | | | | |
| Inotropes | 17 | 17 (12.1) | 8 | 7 (5.0) |
| RVAD | 3 | 3 (2.1) | 1 | 1 (0.7) |
| Arterial Thromboembolism | 0 | 0 | 2 | 2 (1.4) |
| Venous Thromboembolism | 4 | 4 (2.9) | 3 | 3 (2.1) |
| Renal Dysfunction | 8 | 8 (5.7) | 6 | 5 (3.6) |
| Psychiatric event | 5 | 5 (3.6) | 4 | 4 (2.9) |
| Myocardial Infarction event | 0 | 0 | 1 | 1 (0.7) |
| Hypertension | 1 | 1 (0.7) | 0 | 0 |
| Hepatic dysfunction | 3 | 3 (2.1) | 1 | 1 (0.7) |
| Hemolysis event³ | 1 | 1 (0.7) | 1 | 1 (0.7) |

¹4 procedures were not included: elective hysterectomy, elective repair of hemorrhoids, HVAD® exchange and RVAD placement.

²Transfusion criteria include: $\geq 20\text{cc/kg}$ packed red blood cells (PRBC) within any 24 hour period during the first 7 day post implant and any transfusion of packed red blood cells (PRBC) after 7 days following implant with the Investigator recording the number of units given.

³Two cases were excluded: 1 case hemolysis < 72 hours post-implant; 1 case hemolysis occurring in the presence of tPA/Integrillin for VAD thrombosis

The majority of infections did not involve the driveline or cause sepsis. The local, non-device category encompasses a host of sites, including the urinary tract, lungs, sinuses, IV punctures, colon and skin. Infections involving the driveline exit site were more common after hospital discharge (> 30 days). Similarly, subjects were somewhat more likely to experience sepsis from 31-180 days (5.0% of subjects) than perioperatively (2.1%). Nearly a third (11/32) of the supraventricular arrhythmias were bouts of atrial fibrillation, requiring drug therapy. Nearly all the ventricular arrhythmias were ventricular tachycardia. AICD shocks were recorded in 24/29 episodes of ventricular arrhythmia and 2/29 received external cardioversion. Nearly all patients with a reported episode of ventricular tachycardia were subsequently placed on amiodarone.

Respiratory problems were more common in the perioperative period, declining from 26/34 events at 0-30 days to about one-third that number (8/34) from 31-180 days. Subjects were more likely to experience right heart failure events in the perioperative period (20/29). The most common treatment for right heart failure was the use of inotropic drugs and the pulmonary vascular dilator, nitric oxide (25/29). Three subjects required an RVAD and a fourth was exchanged for a pneumatic biVAD at 75 days post-implant. Ischemic strokes (ICVA) were more common overall (10/14 events) and occurred with greater frequency in the perioperative period (7/9 perioperative strokes). Four hemorrhagic strokes (HCVA) were recorded. Three of these resulted in deaths. TIAs were more common in the 31-180 day period (5/7 TIA events). While HCVAs were generally fatal (75%) they were most often associated with hypertension (MAP > 90 mm Hg). Three of the 4 HCVAs had a mean arterial pressure of ≥ 95 mm Hg at the time of the stroke and the one normotensive patient was septic and had an INR of 2.7 (high normal range).

Overall 70% of the patients who experienced ICVAs were transplanted or remained eligible. It is noteworthy that 6/10 ICVA events occurred within 48 hours of implant and may have been related to surgical procedural factors, such as ragged coring of the myocardium for inflow insertion or incomplete device de-airing. These issues were addressed by improvements to the coring tool and by site retraining. The overall stroke survival for the combined ICVAs and HCVAs on the original device was 77% (10/13 patients).

Venous thrombosis occurred in 5% of subjects. Most of these were cases of DVT in the lower extremities. In the arterial thromboembolism category, a case of VAD thrombosis was treated with tPA and resolved and in another case a clot was removed from the left main coronary artery following cardiac catheterization. A third case appeared to involve a shower of small emboli to the periphery.

No subject required permanent dialysis. Psychiatric events were recorded for nine subjects (6.4%). All recovered without sequelae. Two hemolysis events were detected by strict INTERMACS criteria in the absence of VAD thrombosis. These resolved spontaneously.

One subject experienced a myocardial infarction and one subject had a hypertensive event during the perioperative period. Hepatic dysfunction was noted in four subjects.

Adverse events were generally more common in the perioperative period.

SERIOUS ADVERSE EVENTS

A total of 452 serious adverse events on the original device occurred in 118 (84.3%) subjects (Table 5). A total of 287 INTERMACS defined events met the definition of an SAE, and 164 INTERMACS "other" events met the definition of an SAE.

Table 5: Summary of Serious Adverse Events (HeartWare® System N=140)

| Serious Adverse Events (SAEs) | Number of SAEs | Subjects N (%) |
|-------------------------------|----------------|----------------|
| Total Serious Adverse Events | 452 | 118 (84.3) |
| INTERMACS | 287 | 98 (70.0) |
| "Other" | 164 | 75 (53.6) |
| UADE | 1 | 1 (0.7) |

Device Exchange

Device exchange occurred in 7 patients (7/140, 5.0%) in the SAF population during the period 180 days post-implant. Of these 7 exchanges, 3 were resultant from retained tissue being pulled into the pump from the ventricle in the very early post-operative period and were deemed to be procedure related, 2 were exchanged due to thrombus inside the pump, one was exchanged for a high power event of unknown cause and one due to latent right heart failure which caused the patient to require a biventricular support system.

Device Malfunctions

A device malfunction is defined as a failure of one or more of the components of the HeartWare® System, which either directly causes or could potentially, cause or induce a state of inadequate circulatory support (low cardiac output state) or death. There was information on 26 malfunctions from 20 subjects entered into the clinical database during the study period (Table 6).

Table 6: Malfunctions by Suspected Component

| HeartWare® System N=140 Device Component ID | Events N (%) |
|--|-----------------|
| LVAD | 7 (5.0) * |
| Controller | 7 (5.0) |
| Battery | 1 (0.7) |
| Battery Charger | 0 |
| Monitor | 0 |
| Driveline | 2 (1.4) |
| Controller AC Adapter | 6 (4.3) |
| Other Component | 3 (2.1) |

*Described in Pump Exchange section

Neurological Events

This section contains certain neurological event data available on the HeartWare Ventricular Assist System. A comparison of the bridge-to-transplant clinical trial data to that published by Miller, et al.¹ and Pagani, et al.² is shown below. Comparisons of the adverse events recorded in HeartWare trial patients implanted with non-sintered HVAD® pumps through August 23, 2010 and in the perioperative period are shown in Tables Table 7 and Table 8 respectively. August 23, 2010 corresponds to the date of the last enrolled patient's last visit.

Table 7: HeartWare BTT Neurological Event Rates Compared to Literature

| | HeartWare BTT | | Miller et al. | | Pagani et al. | |
|---------|---------------------|-------------------------|---------------------|------------|---------------------|------------|
| | Subjects Affected % | Events PPY [†] | Subjects Affected % | Events PPY | Subjects Affected % | Events PPY |
| Overall | | 0.28 | | 0.45 | | 0.28 |
| TIA | 4.3 | 0.08 | 3.8 | 0.10 | 2.1 | 0.04 |
| ICVA | 7.1 | 0.12 | 6.8* | 0.15 | 5.7* | 0.09 |
| HCVA | 4.3 | 0.07 | 2.3 | 0.05 | 3.2 | 0.05 |
| Other | 0.7 | 0.01 | 6.0 | 0.16 | 5.3 | 0.09 |

[†] Event rates for the HVAD® were calculated using 84.9 patient years.

* Includes one spinal cord infarct event.

Table 8: HeartWare BTT Early Neurological Event Rates Compared to Literature

| | Patients Affected (%) | | | Event Rate (events PPY) | | |
|-------|-----------------------|--------|--------|-------------------------|--------|--------|
| | 0-30 Days | | | 0-30 Days | | |
| | HW | Miller | Pagani | HW [†] | Miller | Pagani |
| ICVA | 5.0 | 3.8 | 2.8 | 0.63 | 0.49 | 0.37 |
| HCVA | 1.4 | 1.5 | 1.4 | 0.18 | 0.20 | 0.18 |
| TIA | 1.4 | 1.5 | 1.1 | 0.18 | 0.20 | 0.14 |
| Other | 0.7 | 2.3 | 1.4 | 0.09 | 0.29 | 0.18 |

[†] Event rates for the HVAD® were calculated using 11.2 patient years.

¹ Miller et al. New England Journal of Medicine; August 30, 2007

² Pagani et al. Journal of the American College of Cardiology; July 21, 2009

A higher level of perioperative ischemic stroke events was seen with the HeartWare System in this initial cohort of patients. Forty percent of the ischemic stroke patients were ultimately transplanted. Thirty percent of ischemic stroke patients lost transplant eligibility while thirty percent were alive and remained eligible for transplant. One hundred percent of the hemorrhagic stroke patients died or lost transplant eligibility as a result of these neurological events.

During the continued access phase (CAP), data was captured on patients receiving HVAD® pumps with sintered inflow cannula. This device modification is incorporated in the PMA approved, commercial device and is intended to allow for increased tissue ingrowth around the inflow cannula. The stroke incidence in patients receiving these devices is lower than that of patients receiving devices with the non-sintered inflow cannula. The adverse event information for the CAP patients who received sintered versus non-sintered cannula pumps is shown below.

Table 9: Perioperative Neurologic Events for Sintered vs. Non-Sintered Pumps in CAP Cohort

| INTERMACS Category Adverse Events | Sintered (N = 60) | | | Non-Sintered (N = 132) | | |
|--------------------------------------|--------------------|----------------------|--------------------------|------------------------|----------------------|-----------------------|
| | (0-30 Days) Pts | (0-30 Days) % Pts | Events (0-30 Days) | (0-30 Days) Pts | (0-30 Days) % Pts | Events (0-30 Days) |
| Ischemic CVA | 0 | 0.0 | 0 | 4 | 3.0 | 4 |
| Hemorrhagic CVA | 2 | 3.3 | 2 | 3 | 2.3 | 3 |
| TIA | 0 | 0.0 | 0 | 2 | 1.5 | 2 |

Table 10: Late Neurologic Events for Sintered vs. Non-Sintered Pumps in CAP Cohort

| INTERMACS Category Adverse Events | Sintered (N = 60) | | | | Non-Sintered (N = 132) | | | |
|--------------------------------------|-------------------|-------|----------------------------|--------------------------|------------------------|-------|----------------------------|--------------------------|
| | Pts | % Pts | Events (0 – 30 Days) | Events (> 30 Days) | Pts | % Pts | Events (0 – 30 Days) | Events (> 30 Days) |
| Ischemic CVA | 2 | 3.3 | 0 | 2 | 11 | 8.3 | 4 | 7 |
| Hemorrhagic CVA | 4 | 6.7 | 2 | 2 | 10 | 7.6 | 3 | 9 |
| TIA | 1 | 1.7 | 0 | 1 | 3 | 2.3 | 2 | 1 |

A multivariate analysis³ was performed to identify the most significant factors associated with at least one stroke (ICVA and HCVA) event, and a stroke mitigation strategy was developed. To mitigate the risk of stroke with HVAD® pumps, clinicians should adhere to the following patient management guidelines:

- Maintain MAP at <85 mm Hg as tolerated. The HVAD® pump is sensitive to both preload and afterload
- Ramp speed and flows more slowly during the first few weeks (e.g., 30 days) post-implant to avoid excessive hemodynamic forces that may damage fragile blood vessels that have undergone remodeling secondary to the lower pressures and reduced flow associated with medically-treated heart failure. There is no apparent need to exceed a cardiac index of 2.6 L/min/m² until patients have fully recovered from the implant surgery and physical performance improves. A cardiac index of 2.6 L/min/m² is the lower limit of normal for a healthy adult.
- Maintain anticoagulation within the recommended INR range of 2.0-3.0.
- Check for ASA resistance with a reliable test (e.g., VerifyNow) and adjust ASA mono-therapy accordingly or consider combination therapy such as ASA 81 mg plus Aggrenox (ASA plus extended-release dipyridamole) or daily ASA 81 mg plus Plavix 75 mg. In general, mono-therapy with ASA is not encouraged in the absence of testing for resistance.

³More than thirty dichotomous covariates were considered as critical risk factors. Each covariate was assessed independently as a predictor (univariate analysis) and covariate influence was measured with odds-ratios and accompanying p-values using the Cochran-Mantel-Haenszel test. Covariate reduction was performed based on univariate analysis results and the impact of potential multicollinearity. In addition, important interaction terms were considered. A logistic regression analysis was performed with the remaining covariate terms to generate a model for predicting stroke outcomes.

ADDITIONAL CLINICAL DATA

Additional clinical data have been collected on the HeartWare VAS from an ongoing, randomized, controlled destination therapy trial (ENDURANCE) that should complete follow up in May 2014. Destination Therapy is for patients with end-stage heart failure who are 10 years older on average and not eligible for cardiac transplantation. Although the ADVANCE trial evaluated patients who were candidates for heart transplant, ENDURANCE does provide concurrent control adverse event information in a set of heart failure patients receiving mechanical circulatory support.

A subset of the unadjudicated data from ENDURANCE up to 180 days following implant is included in

Table 11. Of the patients who were implanted as of the cutoff date of May 6, 2012, 82 of 178 sintered HVAD® patients (46.1%) and 91 of 140 Control patients (65.0%) had been implanted at least 180 days prior to the cutoff date. Since pumps with sintered inflows are the only pumps marketed under this PMA by HeartWare, results for these HVADs are compared to the control device.

**Table 11: Select Adverse Events from ENDURANCE Trial to 180 days Post-Implant
(Data cut-off May 6, 2012)**

| Site Reported Event (0-180 Days) | HVAD Sintered [% (n/N)] | Control [% (n/N)] |
|---|------------------------------------|------------------------------|
| Death | 14.0 (25/178) | 13.6 (19/140) |
| Neurological events | | |
| ICVA | 6.7 (12/178) | 4.3 (6/140) |
| HCVA | 5.1 (9/178) | 0.0 (0/140) |
| TIA | 2.2(4/178) | 2.9(4/140) |
| Device Exchange | 3.9 (7/178) | 5.7 (8/140) |
| Device Thrombus | 2.8 (5/178) | 7.1 (10/140) |
| Exchange | 1.7 (3/178) | 5.7 (8/140) |
| Med. Treated | 1.1 (2/178) | 1.4 (2/140) |
| Bleeding | | |
| Bleeding requiring re-operation | 11.8 (21/178) | 12.9 (18/140) |
| Bleeding requiring transfusion \geq 4 units within 7 days post implant | 15.2 (27/178) | 19.3 (27/140) |
| Infection | 27.0 (48/178) | 30.0 (42/140) |

SECONDARY ENDPOINTS:

Overall survival in the HeartWare group was 94.3% (132/140) in the safety population and 91.2% in the control group at 180 days, as displayed in Table 12.

Table 12: Overall Survival at 180 days

| | HeartWare® System N=140 | INTERMACS N=499 |
|-------------------------|----------------------------|--------------------|
| Survival at 180 Days | N (%) | N(%) |
| Safety Population | | |
| Survival | 132/140 (94.3) | 455/499 (91.2) |
| Died | 8/140 (5.7) | 44/499 (8.8) |
| Per Protocol Population | | |
| Survival | 130/137 (94.9) | 455/499 (91.2) |
| Died | 7/137 (5.1) | 44/499 (8.8) |

Survival differs from the primary analysis of success in that subjects who have a device exchange are not censored at the time of exchange, but continue to accrue time until the endpoints of transplant, death or explant for recovery.

QUALITY OF LIFE: KCCQ AND EUROQOL

Kansas City Cardiomyopathy Questionnaire (KCCQ): At baseline, 128/140 (91.4%) patients were able to complete the KCCQ and at month 6 there were 88 patients available to complete the test (39 had received a transplant, six had died, seven had met an endpoint receiving a device exchange) (Table 13). Of the 88 patients available for assessment, 74 patients had data at month 6. Reasons for missing the month 6 data included: 9 of 14 with poor compliance/missed visit (8 of 9 of these from a single site and 1 of 9 had a prior ICVA with MRS score of 2), 2 were too sick, 1 had no form available, 1 had been transplanted within the 14 day visit window, and 1 had refused. Seventy patients (70) had both baseline and month 6 data. For these 70 patients who were on HVAD® therapy continuously for 180 days had a 31 point improvement in KCCQ Overall Summary Score, over the 180 day period.

Table 13: KCCQ - Overall Summary Score

| KCCQ | Baseline | Month 6 | Change from Baseline |
|-----------|-------------|-------------|----------------------|
| N | 128 | 74 | 70 |
| Mean (SD) | 34.9 (18.9) | 67.5 (20.4) | 30.9 (26.5) |
| Median | 31.5 | 71.4 | 34.5 |
| Min, Max | 0.0, 84.1 | 19.3, 100.0 | -49.4, 80.5 |
| 95% CI | 31.6, 38.2 | 62.8, 72.2 | 24.6, 37.3 |

European Quality of Life (EuroQol): At baseline, 130/140 (92.9%) of patients were able to complete the test, and at month 6 there were 88 patients available to complete the test, (39 had received a transplant, six had died, seven had met an endpoint receiving a device exchange) (Table 14). Of the 88 patients available 75 had data at month 6. Reasons for missing the month 6 data included: 9 of 13 with poor compliance/missed visit (8 of 9 of these from a single site and 1 of 9 had a prior ICVA with MRS score of 2), 2 were too sick, 1 had been transplanted within the 14 day visit window, and 1 had refused. Seventy-two patients (72) had both baseline and month 6 data showing an improvement of 30 points over the 180 day period.

Table 14: EuroQol (EQ-5D) - Summary of Quality of Life

| EuroQol | Baseline | Month 6 | Change from Baseline |
|------------------------------|-------------|-------------|----------------------|
| Overall Summary Score | | | |
| N | 130 | 75 | 72 |
| Mean (SD) | 39.7 (23.5) | 69.8 (19.8) | 29.5 (25.2) |
| Median | 40.0 | 75.0 | 30.0 |
| Min, Max | 0.0, 92.0 | 4.0, 100.0 | -36.0, 80.0 |
| 95% CI | 35.6, 43.7 | 65.2, 74.4 | 23.6, 35.4 |

FUNCTIONAL ANALYSES: 6 MINUTE WALK

6 Minute Walk: Of the 132 patients assessed for the 6-minute walk test, the mean distance walked was 89.4 meters. Seventy-Five (75) of the 88 patients on pump at month 6 completed the test (Table 15 and Figure 3). Reasons for missing the 6 minute walk test at month 6 included: 9 of 14 with poor compliance/missed visit (8 of 9 of these from a single site and 1 of 9 had a prior ICVA with MRS score of 2), 2 were too sick, 1 had no form available, 1 had been transplanted within the 14 day visit window, and 1 had refused. These 75 patients showed a mean distance walked of 246 meters, a mean change of 150 meters from baseline.

Table 15: Functional Status – 6 Minute Walk

| 6 Minute Walk | Baseline | Month 6 | Change from Baseline |
|----------------------------------|--------------|---------------|----------------------|
| Distance Walked in Meters | | | |
| N | 132 | 75 | 74 |
| Mean (SD) | 89.4 (141.3) | 246.0 (203.9) | 150.1 (214.1) |
| Median | 0.0 | 274.0 | 108.3 |
| Min, Max | 0.0, 600.2 | 0.0, 991.8 | -273.1, 700.9 |
| 95% CI | 65.1, 113.7 | 199.1, 292.9 | 100.5, 199.8 |

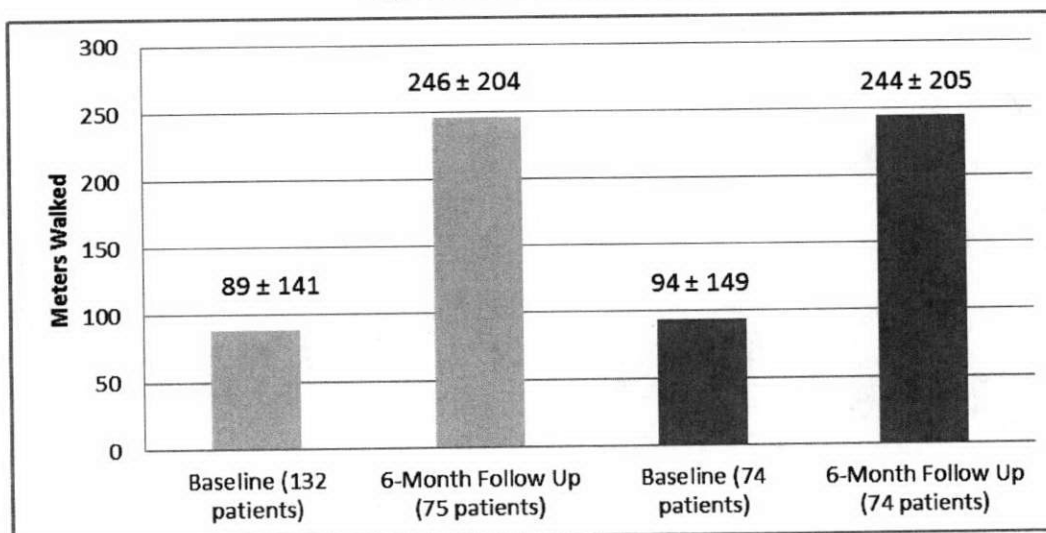
Figure 3: 6 Minute Walk Test

Table 16 shows a breakdown of results of patients who walked at both baseline and at 6 months as well as those patients that did not walk at baseline but did walk at 6 months.

Table 16: 6 Minute Walk – Breakdown of Patients Walking vs. Not Walking at Baseline

| HeartWare® System Patients | Baseline (m) | Month 6 (m) |
|---|------------------|------------------|
| Patients walking at baseline and at 6 months | 260 ± 140 (n=25) | 338 ± 202 (n=25) |
| Patients NOT walking at baseline (for any reason) but walking at 6 months | N/A | 333 ± 125 (n=30) |

7.5 Overall Conclusions from Clinical Data

The HeartWare® System bridge-to-transplant study (ADVANCE) was a multi-center, prospective, contemporaneous control trial. The purpose of this study was to evaluate the safety and effectiveness in patients listed for cardiac transplantation with refractory, advanced heart failure at risk of death. The primary endpoint was success at 180 days which is defined as alive on the originally implanted HVAD® Pump or transplanted or explanted for recovery.

The analysis of the primary endpoint yielded non-inferiority of the HeartWare® System to the INTERMACS control. The 95% one-sided UCL on the difference in success rates was 4.5% for the Safety Group and 0.9% for the Per Protocol Group. Each of these limits was less than the 15% non-inferiority margin (p-value <0.0001).

- *The pre-specified primary endpoint was achieved.*
- *Both quality of life and functional capacity showed improvements following implant of the HVAD® Pump.*
- *The HeartWare System has an adverse event profile that supports its safe use for bridge to transplant patients.*

8.0 SYSTEM COMPONENT OVERVIEW

See Appendix B for a complete list of system components.

8.1 HeartWare® Ventricular Assist System

The HeartWare® System consists of a blood pump with an integrated, partially sintered inflow cannula; a 10mm diameter gel impregnated polyester outflow graft, and a percutaneous driveline. A strain relief is used on the outflow graft to prevent kinking and secures the outflow graft to the pump. The driveline cable is wrapped with woven polyester fabric to encourage tissue in-growth at the skin exit site. The small, wearless pump has a displaced volume of 50cc and weighs 160 grams. The pump has one moving part, an impeller, which spins blood to generate up to 10 L/min of flow. There are two motors in the pump housing with one motor providing redundancy. A short integrated inflow cannula is inserted into the left ventricle and the outflow graft connects the HVAD® Pump to the aorta. A sewing ring attaches to the myocardium and allows for pump orientation adjustments intraoperatively. The device size and short inflow cannula allow for pericardial placement, which eliminates the need for abdominal surgery and device pockets (Figure 4).

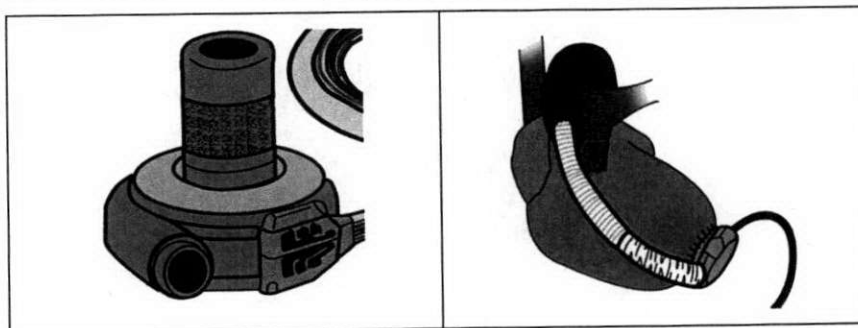


Figure 4: HVAD® Pump and left ventricular (LV) cannulation

8.2 HeartWare® Controller

The controller (Figure 5) is a microprocessor unit that controls and manages HeartWare® System operation. It sends power and operating signals to the blood pump and collects information from the pump. The percutaneous driveline is connected to the controller, which must always be connected to two power sources - an AC adapter or DC adapter and/or rechargeable batteries. The controller's internal, non-replaceable, rechargeable battery is used to power an audible "No Power" alarm when both power sources are disconnected. The controller interfaces with the monitor through a data port.

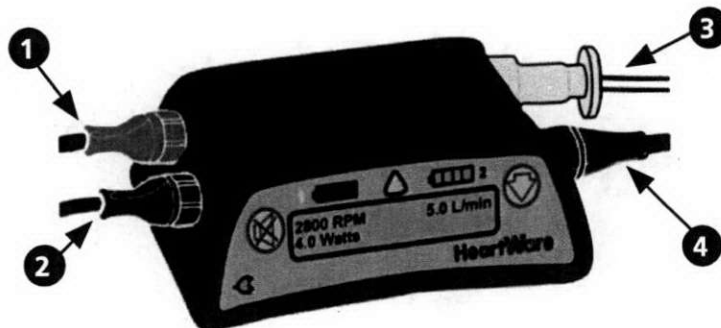


Figure 5: Controller

1. Monitor Connection
2. Power Connection
3. Driveline Connection
4. Power Connection

CAUTION: ONLY use HeartWare® Controllers on one patient to avoid risks associated with an inadvertent mismatch of controller pump speed settings.

8.3 HeartWare® Monitor

The monitor (Figure 6) is a touch screen tablet that uses proprietary software to display system performance and to permit adjustment of selected controller parameters. When connected to a controller, the monitor receives continuous data from the controller and displays real-time and historical pump information. The monitor also displays alarm conditions.

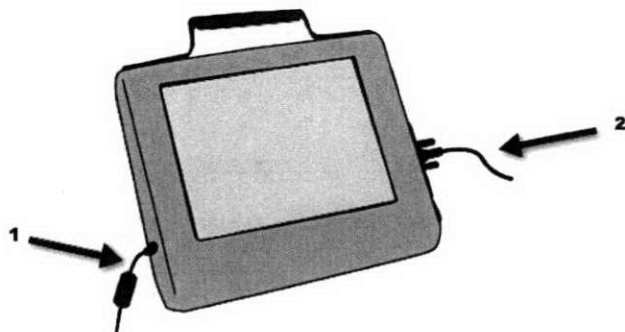


Figure 6: Monitor

1. Power Cord
2. Monitor/Controller Connection

8.4 HeartWare® Controller Power Sources

The controller requires two power sources for safe operation: either two batteries, or one battery (Figure 7) and an AC adapter (Figure 8) or DC adapter (Figure 9). While active, patients will typically use two batteries. While relaxing or sleeping, patients should use power from an electrical outlet (AC adapter) because it provides power for an unlimited period of time. The batteries should be exchanged when their charge falls below 25% capacity. Spare, fully charged batteries should always be available.



Figure 7: Battery

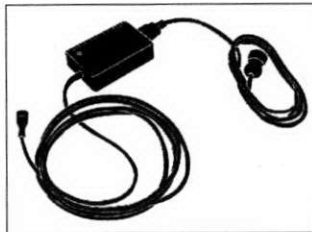


Figure 8: AC adapter

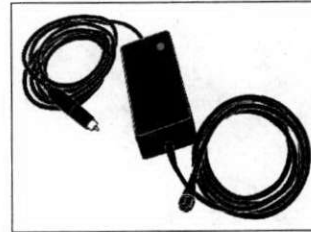


Figure 9: DC adapter

WARNING! NEVER disconnect both power sources (batteries and AC or DC adapter) at the same time since this will stop the pump. At least one power source must be connected at all times.

8.5 HeartWare® Battery Charger

The battery charger (Figure 10) is used to simultaneously recharge up to four batteries. It takes approximately 4 to 5 hours to fully charge a depleted battery.

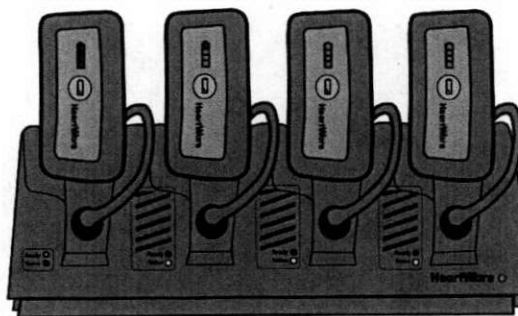


Figure 10: Battery charger

8.6 Equipment for Implant

Figure 11 shows the HeartWare® System components used at implant (provided ETO sterilized).

- **HVAD® Pump**
- **Outflow graft** – a 10mm diameter gel impregnated graft
- **Strain relief** – to prevent outflow graft kinking
- **Sewing ring**– to secure the HVAD® Pump to the left ventricle
- **Driveline cap** – to protect the driveline connector when tunneling

- **Inflow cap** – to cover the pump inflow cannula after the wet test and prior to implantation
- **Driveline extension cable** - used during the pre-implant wet test to keep the non-sterile controller isolated from the sterile field



Figure 11: Components used at implant

1. HVAD® Pump
2. Outflow graft
3. Sewing ring (made of titanium and polyester)
4. Driveline cap
5. Strain relief
6. Inflow cap
7. Driveline extension cable

A set of surgical tools (provided ETO sterilized) is also required for implantation of the device (Figure 12).

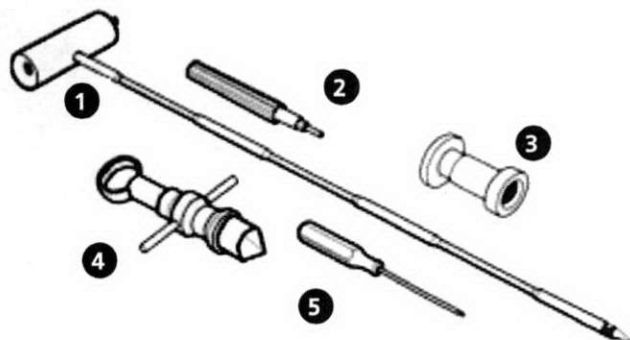


Figure 12: Surgical tools

1. **Tunneler** – to tunnel the pump's percutaneous driveline through the skin to the exit site
2. **Sewing ring wrench** – to tighten the screw on the sewing ring
3. **Driveline cover** – to cover the driveline connection to the controller
4. **Apical coring tool** – to core the LV apex
5. **Hex driver** – to secure the strain relief and outflow graft to the HVAD® Pump

All tools and accessories used during implantation are for single-use only.

9.0 PRINCIPLES OF OPERATION

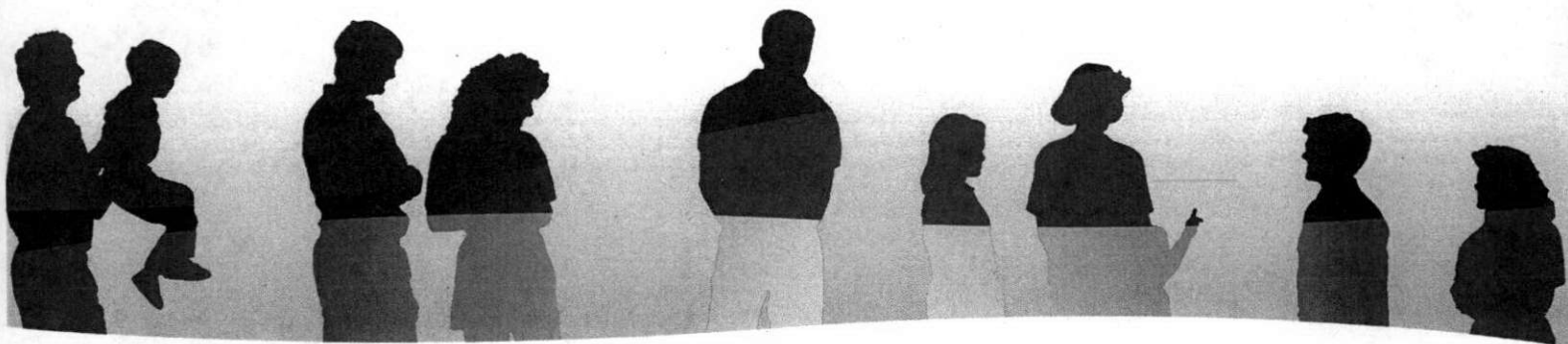
9.1 Background

Continuous flow pumps contain a rotating impeller that adds energy to the blood by converting the rotational kinetic energy into mechanical energy (Figure 13). Impeller blades push the fluid through the pump using hydrodynamic and centrifugal forces. The net effect is to build up the fluid pressure, sometimes referred to as pump head (i.e., related to the differential pressure across the device) or just head, such that the fluid is moved from the inlet to the outlet of the pump. Pump head is the difference between the afterload and the preload. Energy to rotate the impeller is provided through electromagnetic coupling between permanent magnets (rotor magnet) attached or enclosed within the impeller and the motor stators. The motor stators consist of coils of wire that are sequentially charged by electrical current, turning the coils into electromagnets. These electromagnets have the effect of



HeartWare® Ventricular Assist System

Patient Manual



CAUTION: Federal law restricts this device to sale by or on the order of a physician.

IMPORTANT

Please read this entire manual before using the HeartWare® Ventricular Assist System outside of the hospital. It is not safe to use the system away from trained professionals until you understand the information in this manual.

CONTACT INFORMATION

All problems should be promptly reported to medical or technical personnel. Before you leave the hospital, add names and contact information below. It is very important to keep this information available in case something happens to you or to your HeartWare® System.

TECHNICAL ASSISTANCE FOR HEARTWARE® VENTRICULAR ASSIST SYSTEM

| | | | |
|---------------|-----------------|----------------|-----------------|
| _____ Name | _____ Office | _____ Pager | _____ Mobile |
| _____ Name | _____ Office | _____ Pager | _____ Mobile |

MEDICAL ASSISTANCE

| | | | |
|---------------|-----------------|----------------|-----------------|
| _____ Name | _____ Office | _____ Pager | _____ Mobile |
| _____ Name | _____ Office | _____ Pager | _____ Mobile |

AMBULANCE

| | |
|------------------|-----------------------|
| _____ Company | _____ Phone Number |
|------------------|-----------------------|

QUICK REFERENCE GUIDE FOR ALARMS

When an alarm occurs, two lines of text appear in the Controller Display. The first line tells you what the alarm is, and the second line tells you what to do. The chart below shows all potential alarms you may see on your controller.

| Alarm Type | Alarm Display (line 1) | Action (line 2) |
|-----------------------------|---|-------------------|
| | <no message> | <no message> |
| | When both power sources (2 batteries or 1 battery and an AC adapter or DC adapter) are removed, <u>NO</u> message will display on the controller. The "No Power" alarm will sound but the Alarm Indicator on the controller WILL NOT light. This indicates your pump has stopped. You should immediately connect two power sources. | |
| | VAD Stopped | Connect Driveline |
| | VAD Stopped | Change Controller |
| | Critical Battery 1 | Replace Battery 1 |
| | Critical Battery 2 | Replace Battery 2 |
| | Controller Failed | Change Controller |
| Medium (Flashing Yellow) | Controller Fault | Call |
| | Controller Fault | Call: ALARMS OFF |
| | High Watts | Call |
| | Electrical Fault | Call |
| | Low Flow | Call |
| | Suction | Call |
| Low (Solid Yellow) | Low Battery 1 | Replace Battery 1 |
| | Low Battery 2 | Replace Battery 2 |
| | Power Disconnect | Reconnect Power 1 |
| | Power Disconnect | Reconnect Power 2 |

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1 GLOSSARY OF TERMS


If you have any questions or need more information about the terms defined below, please ask your doctor or VAD coordinator.

A

AC Adapter: An adapter that uses power from an electrical outlet to run the controller.

Alarm Adapter: A small red adapter, that when inserted into the controller, will silence the "No Power" alarm if power is removed from a controller that is no longer in use.

Alarm Mute Button:  A button on the front of the controller that silences low and medium level alarms. When pressed and held for 5 seconds simultaneously with the Scroll Button, it will also silence the "No Power" alarm if power is removed from a controller that is no longer in use.

Alarm Indicator:  A button on the front of the controller that lights when one or more alarm conditions occur. The indicator changes colors depending on the severity of the alarm and always displays the most severe alarm in the case of multiple alarms.

Anticoagulants: Drugs that increase the time it takes blood to clot.

B

Battery: One of the power sources used to run the pump. Two batteries or one battery and an AC adapter or DC adapter are required at all times.


Battery Charger: Unit used to charge batteries. Up to four batteries may be charged at a time.


Battery Capacity Display: The Battery Capacity Display on the battery uses four green lights to show how much power remains in the battery. Each green light represents approximately 25% of available power. When a battery is charged and ready for use, all four lights will be on. As the battery loses charge, fewer lights will appear.

C

Cardioversion: Controlled electrical shock used to return the heart to a normal beating pattern.

Controller: A small computer that operates the pump and makes sure it is working correctly. It warns the user with words, lights and sounds if there is a problem.

Controller AC/DC Indicator:  The Controller AC/DC Indicator will be green if you are using the AC adapter or DC adapter to power the controller.

Controller Battery Indicators:  The Controller Battery Indicators are located on the top of the controller and are labeled "1" and "2". Either the "1" or "2" light will be lit, depending upon which port is providing primary battery power to the controller. The Controller Battery Indicators tell you approximately how much power remains in each battery. When a battery is fully charged, all four lights will be on. As the battery loses charge, fewer lights appear.

D

DC Adapter: An adapter that uses power from an electrical outlet in an automobile to run the controller.

Driveline: The cable that passes through the skin and connects to the implanted pump and to the external HeartWare® System components.

Driveline Cover: A small, white cover that slides over the pump/controller connection to protect it and keep it clean.

E

Exit Site: Location where the driveline passes through the skin.

H

HeartWare® System: All of the components, both internal and external, needed to implant and run the HVAD® Pump.

High Alarm: The most serious audio and visual (flashing red) alarm. High priority alarms require immediate attention.

HVAD® Pump: A pumping device that sits inside your chest and is connected directly to your heart. It helps your heart pump blood throughout the rest of your body.

I

Impeller: The only moving part of the pump. As the impeller spins it moves blood from the heart to the rest of the body.

L

Low Alarm: An audio and visual (solid yellow) alarm that instructs you to either replace a low battery or to reconnect to a power source (battery, AC adapter or DC adapter).

L/min: Liters per minute. Measurement of how much blood the pump is pumping through the body in a minute. Shown on the Controller Display.

LVAD: Left ventricular assist device. A mechanical pump that helps the left side of the heart pump blood through the rest of the body.

LVAS: Left ventricular assist system. A heart assist system that includes an implanted pump as well as an external controller with associated power sources (batteries, AC adapter, and DC adapter) and accessories.

M

Medium Alarm: An audio and visual (flashing yellow) alarm that requires you to notify your doctor or VAD coordinator.

Multiple Alarms: Condition in which there are two or more alarms occurring at the same time.

N

No Power Alarm: An audible only alarm that sounds when both power sources are removed from the controller.


P

Pump: A device (also known as an LVAD) that moves blood from your heart to other parts of your body. The pump is implanted at the base of your heart during surgery.

R

RPM: Revolutions per minute. The number of times the impeller in the pump spins in a minute. Shown on the Controller Display.

S

Scroll Button:  Located on the right side of the controller, the Scroll Button is used to see all active alarms and pump information (RPM, L/min, Watts) on the Controller Display. The Scroll Button will also clear resolved medium alarms from the Controller Display, will silence a “No Power” alarm when pressed with the Alarm Mute Button (see Alarm Mute Button), and will brighten the Controller Display.

Shower Bag: A bag that holds the controller and two batteries during a shower.

T

Test Button: A button on the battery that displays battery capacity when pressed.

V

VAD: Ventricular Assist Device. A mechanical device that assists the heart.

W

Watts: Measurement of the amount of electricity used to run the pump. Shown on the Controller Display.

2 INTRODUCTION

Congestive heart failure is a condition in which a heart cannot pump enough blood to meet the body's needs. A failing heart works, but not as efficiently as it should. As blood flow leaving the heart slows, blood flow returning to the heart will back-up, causing congestion in the tissues. Along with congestion in the tissues, swelling (edema) often results. Swelling most often occurs in the legs and ankles but it can happen in other parts of the body, too. Fluid may collect in the lungs and interfere with breathing, causing shortness of breath, especially when a person is lying down. Heart failure also affects the kidneys' ability to dispose of waste and extra fluid. Fluid retained by the kidneys increases swelling. People with heart failure cannot exert themselves because they become short of breath and tired. With advanced heart failure, symptoms of tissue wasting and weight loss can occur. Severe heart failure can progress to shock (shock due to inadequate oxygen and nutrients delivered by the heart) and eventual death.

2.1 When Ventricular Assist Devices are Indicated

Doctors use VADs such as the HeartWare® System to treat patients who are waiting to receive a heart transplant and have severe heart failure that has not improved despite using all other treatment methods available.

The HeartWare® System should not be used in patients who cannot take blood thinning medications.

2.2 Why You Should Read this Manual

This Patient Manual will tell you about your HeartWare® System and explain how it works. It also provides information about proper care of the HeartWare® System and what to do in case of an emergency.

In addition to this manual, your physician, nurse or VAD coordinator will provide you with instructions on operating the HeartWare® System and on necessary medical care. Prior to leaving the hospital you should understand how the HeartWare® System works, how to care for the equipment and what to do in emergency situations. If you have any questions after reading this manual, please ask your physician, nurse or VAD coordinator.

2.3 Understanding How Your HeartWare® Ventricular Assist System Works

The HeartWare® System helps your weakened heart pump blood throughout your body. The pump, called the HVAD® Pump, circulates blood by removing it from the left side of your heart and pumping it into your aorta (large blood vessel that carries blood from your heart to the rest of your body). The pump rests inside your chest and two small motors inside the pump circulate the blood (Figure 1). A driveline (electrical wire) exits your skin and connects the pump to a controller. The controller is powered by two batteries or a battery and electricity from the wall or car outlet. The controller operates the pump and tells you if there are any problems with your system. The controller and batteries are contained in a Patient Pack (carrying case).

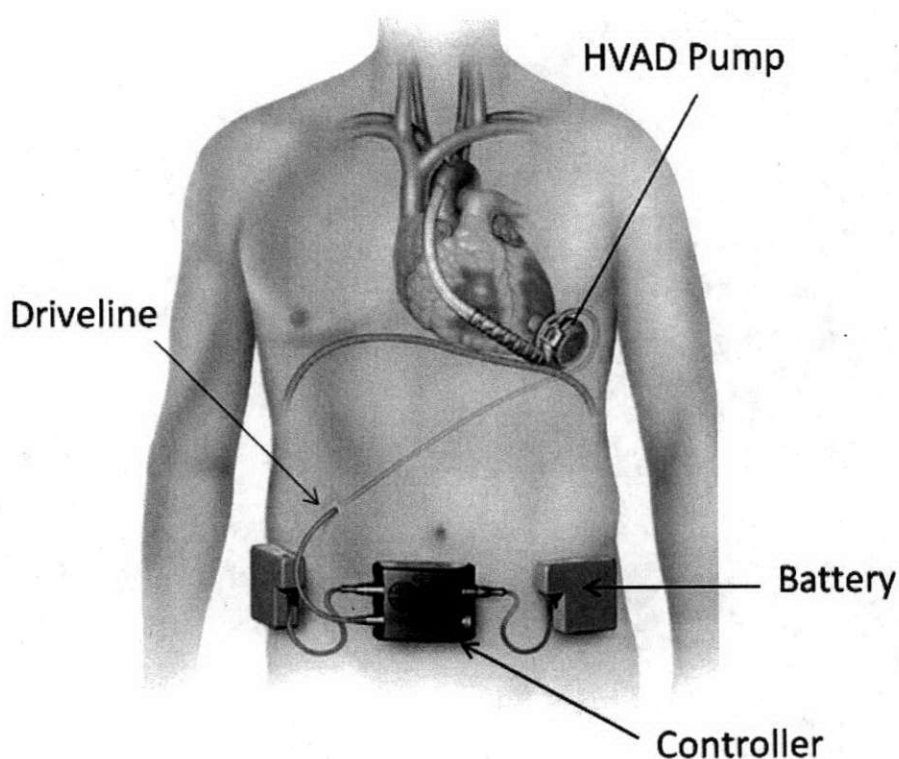



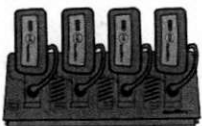
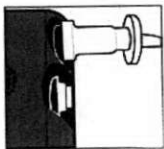





Figure 1: Illustration of an Implanted HVAD® Pump

2.4 HeartWare® Ventricular Assist System Components

| | | |
|------------------------------|---|---|
| HVAD® Pump |  | <p>The pump moves blood from your heart to other parts of your body. The pump is implanted at the base of your heart during surgery.</p> |
| HeartWare® Controller |  | <p>The controller operates the pump and makes sure it is working correctly. It warns you with words, lights and sounds if there is a problem.</p> |
| HeartWare® Battery |  | <p>The battery is used to power the controller and the pump. Two batteries or one battery and an AC adapter or DC adapter are ALWAYS required.</p> |

| | | |
|--|---|--|
| HeartWare® Battery Charger |  | The battery charger charges and tests the batteries. |
| Driveline Cover |  | A small, white cover that slides over the pump/controller connection and protects the controller and pump connector. |
| HeartWare® Controller AC Adapter |  | The AC adapter uses power from an electrical outlet to power the controller and pump. |
| HeartWare® Controller DC Adapter |  | The DC adapter uses power from an electrical outlet in a motor vehicle to power the controller and pump. |
| Alarm Adapter |  | The red alarm adapter is for emergency use only. The adapter is used to silence the "No Power" alarm when power is removed from a controller that is no longer in use. |

Recommended environmental conditions for general use of the HeartWare® System:

- Temperature range within 10°C to 31°C (50°F to 88°F)
- Relative humidity range within 30% to 75%

3 WARNINGS and PRECAUTIONS

3.1 Warnings

1. **WARNING!** Serious and life threatening adverse events, including stroke, have been associated with use of this device. A user must fully consider the risks of this device with that of other treatment modalities before deciding to proceed with device implantation.
2. **WARNING!** Please read this entire manual before using the HeartWare® System outside of the hospital. It is not safe to use the system away from trained professionals until you understand the information in this manual.
3. **WARNING!** DO NOT become pregnant while you have the HeartWare® System. If you are a woman of childbearing age, use birth control if you are sexually active. Blood thinners (which

most LVAS patients receive) have been associated with birth defects. If you do become pregnant, tell your physician and hospital contact person immediately.

4. **WARNING!** DO NOT operate the controller in temperatures less than -4°F (-20°C) or greater than 122°F (50°C) or the controller may fail.
5. **WARNING!** DO NOT disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.
6. **WARNING!** ALWAYS investigate, and if possible, correct the cause of any alarm. Silencing an alarm does not resolve the alarm condition.
7. **WARNING!** ALWAYS keep a spare controller and fully-charged spare batteries available at all times in case of an emergency.
8. **WARNING!** DO NOT attach the alarm adapter to a controller that is connected to a running pump. The alarm adapter silences the "No Power" alarm and should only be attached to a controller that has failed or malfunctioned and is no longer connected to a pump.
9. **WARNING!** DO NOT plug the AC adapter into an electrical outlet that is not properly grounded or you may receive a serious electrical shock.
10. **WARNING!** ALWAYS replace a controller with a blank display and/or no audible alarms.
11. **WARNING!** NEVER disconnect both power sources (batteries, AC adapter, DC adapter) at the same time since this will stop the pump and activate the No Power alarm. At least one power source must be connected at all times.
12. **WARNING!** ALWAYS switch to the backup controller if there is a "Controller Failed" alarm.
13. **WARNING!** DO NOT drop the controller or other equipment. Dropping the controller could cause sudden stoppage of the pump. Dropped equipment should be reported and inspected.
14. **WARNING!** ALWAYS check the controller display for any information regarding an alarm when using loud machinery or in the vicinity of loud noises since under these conditions, the controller and battery alarms may not be audible.
15. **WARNING!** DO NOT have a magnetic resonance imaging (MRI) procedure while implanted with the HVAD® System. Doing so could harm you or cause the pump to stop.
16. **WARNING!** Keep mobile phones at least 20 inches (50 centimeters) away from the controller, as mobile phones may interfere with controller operation.
17. **WARNING!** DO NOT undergo procedures requiring high power electrical treatment (e.g. application of diathermy) while the pump is implanted.
18. **WARNING!** AVOID exposure to therapeutic levels of ultrasound energy. Consult your physician before having lithotripsy procedures to treat kidney stones or any treatments involving high intensity ultrasound. The implanted device may inadvertently concentrate the ultrasound field and cause harm.

19. **WARNING!** AVOID therapeutic ionizing radiation. Consult your physician before having any nuclear medicine procedures or radiation therapy for cancer. Radiation may damage the device and may not be immediately detectable.
20. **WARNING!** DO NOT shower until your physician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare® Shower Bag. If your hearing is impaired and/or you cannot hear the controller alarms without the use of a hearing aid, make sure your caregiver will be close by to hear alarms.
21. **WARNING!** DO NOT plug the controller into an AC wall outlet during showers; it should be connected to two batteries.
22. **WARNING!** DO NOT take a bath or swim.
23. **WARNING!** DO NOT submerge any HeartWare® System component in water.
24. **WARNING!** DO NOT allow water or other fluids to enter the controller, power (AC/DC) adapters, batteries, battery charger, or connectors. If this happens, contact your physician, nurse or VAD coordinator.
25. **WARNING!** AVOID areas with high magnetic forces such as theft detection devices or airport security systems, as these may affect HeartWare® Systems operation.
26. **WARNING!** Damaged equipment should be reported to your VAD coordinator and inspected.
27. **WARNING!** DO NOT use any components other than those supplied by HeartWare with the HeartWare® System, as this may affect HeartWare® System operation.
28. **WARNING!** DO NOT disconnect the driveline or power sources from the controller while cleaning it or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.
29. **WARNING!** NEVER clean the battery charger with the power on, as this may lead to an electrical shock.

3.2 Precautions

1. **CAUTION:** Tell your physician if you have sight or hearing problems. The controller uses words, lights and sounds to tell you how the system is operating and when to seek additional help.
2. **CAUTION:** ALWAYS confirm that the power cables are properly locked to the controller by gently pulling the cable near the connector.
3. **CAUTION:** DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.
4. **CAUTION:** ALWAYS keep all connectors free of liquid, dust and dirt, or the HeartWare® System may not function as intended.
5. **CAUTION:** DO NOT pull, twist or kink the driveline or power cables, especially while sitting, getting out of bed, adjusting the controller or power sources, or when using the shower bag.

6. **CAUTION:** ALWAYS check to be sure the DC adapter works in your motor vehicle. The DC adapter is for use in motor vehicles only and may not fit all motor vehicles.
7. **CAUTION:** Use only HeartWare-supplied power adapters with the HeartWare® System.
8. **CAUTION:** ALWAYS recharge completely depleted batteries within 24 hours to avoid permanent battery damage.
9. **CAUTION:** DO NOT place batteries in water or liquid.
10. **CAUTION:** DO NOT expose batteries to temperatures less than 32°F (0°C) or greater than 113°F (45°C) or the battery may run the pump for less time than usual. To preserve battery life, batteries should be stored at room temperature.
11. **CAUTION:** DO NOT expose batteries to excessive shock or vibration.
12. **CAUTION:** DO NOT disassemble, crush, or puncture a battery.
13. **CAUTION:** DO NOT short the external contacts on a battery.
14. **CAUTION:** ALWAYS keep batteries away from children. Children may be harmed by damaged batteries or components.
15. **CAUTION:** DO NOT use a damaged battery.
16. **CAUTION:** DO NOT touch the fluid if a battery pack is leaking fluid. Dispose of a leaking battery pack. In case of eye contact with fluid, DO NOT rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention.
17. **CAUTION:** DO NOT dispose of a battery in fire or water. Dispose of batteries according to federal, state, and local regulations.
18. **CAUTION:** NEVER use other battery chargers to charge HeartWare® batteries. Other battery chargers may damage the batteries.
19. **CAUTION:** ALWAYS wait until the "Ready" light turns on to disconnect the battery from the battery charger. If this is not followed over consecutive charging cycles, the Battery Capacity Display will not function properly and may convey misleading battery capacity.
20. **CAUTION:** ALWAYS call your clinician for appropriate action if there is a "Controller Fault" high alarm. The controller may need to be replaced with the back-up controller.
21. **CAUTION:** DO NOT attempt to repair or service HeartWare® System equipment. If service is required, contact your physician, nurse or VAD coordinator.
22. **CAUTION:** Use only HeartWare-supplied components with your HeartWare® System.
23. **CAUTION:** DO NOT play contact sports. You may start bleeding or could damage your equipment.
24. **CAUTION:** DO NOT pull, kink or twist the driveline or the power cables. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting controller or power sources, or when using the shower bag.

25. **CAUTION:** ALWAYS keep extra driveline length tucked under clothing or secured with an abdominal binder or dressing. Do not let any portion of driveline hang freely where it might get caught on external items such as doorknobs or the corners of furniture.
26. **CAUTION:** ALWAYS notify your physician promptly if there is drainage, swelling or reddened skin around the driveline exit site, these may indicate an infection.
27. **CAUTION:** DO NOT use prophylactic topical antibiotic ointments such as silver sulfadiazine, betadine, or polymyxin-neomycin-bacitracin ointment. These ointments can injure the tissue adjacent to the exit site.
28. **CAUTION:** ALWAYS examine the driveline for evidence of tears, punctures or breakdown of any of the material during exit site dressing changes. Report any damage to your physician, nurse or VAD coordinator.
29. **CAUTION:** ALWAYS notify your physician promptly, if you notice blood or fluid in the driveline. The section of the driveline inside your body may have been damaged during HVAD® Pump implantation or during another operation. The driveline has built in features that minimize the effect of blood or fluid entering it, so the HVAD® Pump should continue to operate normally. However, your physician should examine the driveline to fully evaluate the situation.

4 POTENTIAL COMPLICATIONS AND RISKS

During the two clinical studies a variety of potential complications were identified. Many of these complications were well known from prior experience with other ventricular assist devices however, it is important that you understand all of the potential complications that may occur with the HeartWare® Ventricular Assist System. Implantation of any ventricular assist device is a major operation requiring general anesthesia, an incision that splits the breast bone, being on a heart-lung machine and a breathing machine. Each of these procedures may lead to serious complications. Complications associated with HeartWare® System use and the percentages of patients who develop these complications are shown in the table below. It is possible that a complication not listed in this table may occur.

WARNING! Serious and life threatening adverse events, including stroke, have been associated with use of this device. A user must fully consider the risks of this device with that of other treatment modalities before deciding to proceed with device implantation.

Complications That May Occur with the HeartWare® System:

| Complication | Percent Chance for Patients to Have this Complication | Result of Having a Complication |
|--------------|---|--|
| Infection | 40% | Hospitalization, medication, death |
| Bleeding | 39% | Hospitalization, blood transfusion, surgery, death |

| Complication | Percent Chance for Patients to Have this Complication | Result of Having a Complication |
|--|--|--|
| Irregular Heart Beat | 32% | Hospitalization, medication, cardioversion*, death |
| Failure of the Right Side of the Heart | 22% | Hospitalization, medication, pump for right side of heart, death |
| Lung Problems | 18% | Hospitalization, medication, ventilator, death |
| HeartWare® System Malfunction/Failure | 16% | Hospitalization, medication, surgery, death |
| Nervous System (brain or nerve) Problems | 15% | Confusion, loss of memory, pain, death |
| Stroke | 12% | Hospitalization, medication, surgery, rehabilitation, death |
| Blood Clots in the Bloodstream | 10% | Hospitalization, medication, death |
| Psychological Problems | 8% | Hospitalization, medication, depression |
| Kidney Problems | 8% | Hospitalization, medication, dialysis, death |
| Liver Problems | 5% | Hospitalization, medication, death |
| Damage to Blood Cells | 3% | Hospitalization, medication |
| Heart Attack | 0.3% | Hospitalization, medication, death |

*Cardioversion: Controlled electrical shock used to return the heart to a normal beating pattern

5 POTENTIAL BENEFITS

The HeartWare® System was designed to assist a failing heart. The potential benefit of having the HeartWare® System is the relief of the symptoms of advanced heart failure while you are waiting for a heart transplant. However, there is no guarantee of this and your symptoms may remain unchanged. As a result of the relief of symptoms of heart failure you will feel stronger and have the ability to be more active.

5.1 How to Decide if a HeartWare® System is Right Treatment for You

Only you, in consultation with your doctor can decide if having the HeartWare® System is right for you. Your doctor will talk with you about the potential benefits and risks of surgery and implantation of the HeartWare® System. Be sure to talk to your doctor about any concerns or questions you may have.

5.2 The Operation to Place the HeartWare® System

Placement of the HeartWare® System requires a major operation. An incision will be made on the breastbone so the surgeons can gain access to your heart. You will be temporarily placed on a heart-lung machine that will do the work of your heart and lungs while the surgeons are placing the HVAD® Pump. Part of the HVAD® Pump will be inside the heart and part will sit in the chest cavity, right next to the heart. An electrical wire called a driveline will be tunneled under the skin and come out through the skin just above the abdomen. The driveline wire will connect the external computer (controller) that runs the pump and the power sources to the implanted pump. After the pump is in place and working, you will be weaned from the heart-lung machine and the incisions will be sutured closed.

Once the HVAD pump has been implanted, you will be taken to the Intensive Care Unit where nurses and doctors will provide you with the level of care you need. You will be on a breathing machine for 12-24 hours and will have to spend some time in the Intensive Care Unit. You will also be connected to several intravenous lines and drainage tubes. During this time you will receive antibiotics to reduce the risk of infection and medications to help keep your heart beating regularly. You may also need to get some blood transfusions. None of these treatments are unusual; they are all intended to reduce the chances that a complication may occur. As you regain your strength, you will be taken off the breathing machine and the intravenous lines and the tubes will be removed. You may also be moved from the Intensive Care Unit to a general hospital floor. While you are in the hospital, you will begin a rehabilitation program designed to help you return to a more active lifestyle. As part of this program, you and your caregiver will be given training on the HeartWare® System. For example, you will be trained on how to use your HeartWare System at home and how to interpret and handle the messages and alarms that may appear on your controller.

5.3 Summary of Clinical Study Information using the HeartWare® System

The HeartWare® System when used to bridge patients to heart transplantation has been evaluated in two clinical studies. The first clinical study was conducted in Europe and Australia. This study included 50 patients of which 90% successfully reached the study success point. The definition of success was:

- Being alive on the HeartWare® System for 180 days or
- Receiving a heart transplant within 180 days of having the HVAD® Pump implanted or
- Having the HVAD® Pump successfully removed after the patient's own heart recovered within 180 days of HVAD® Pump implant.

Six patients from this study still have the HeartWare® System; with the longest patient being on the system 4.5 years.

A second, larger bridge to heart transplantation study was performed in the United States. This study included 140 patients. Of the 140 patients who received the HeartWare® System as bridge to heart transplantation in the United States, 91% reached the study success point. In both these studies, there were improvements in the patients' quality of life and their ability to better perform physical activities with at least 92% of the patients being able to return home after the HeartWare® System was placed. The risks identified in the clinical trials are described in Section 4, Potential Complications and Risks.

6 HEARTWARE® SYSTEM

The HeartWare® System includes the following major components:

1. HVAD® Pump
2. Controller
3. External power – battery, AC adapter and DC adapter
4. Battery charger

6.1 HVAD® Pump

The HVAD® Pump (also known as an LVAD) is small and has one moving part, called an impeller (Figure 2). As the impeller spins it moves blood from the heart to the body. The amount of blood flowing through your pump depends on the speed of the impeller and your blood pressure. The driveline passes through your skin and connects the pump to the controller.

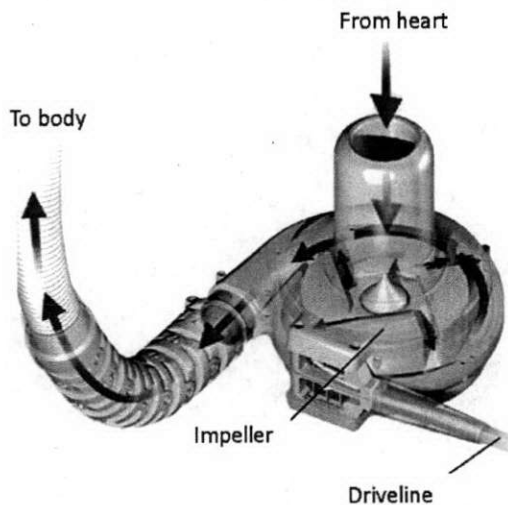


Figure 2: HVAD® Pump with Impeller

6.2 HeartWare® Controller

The controller (Figure 3) operates your pump and makes sure that it is working correctly. The controller is connected to your driveline and should have two power supplies (batteries, AC adapter or DC adapter) connected at all times. The display on the controller gives information about pump performance that includes the blood flow through the pump (L/min), impeller speed (RPM) and the amount of power consumed (Watts). The controller also warns you if there is a problem with your pump or with the power supplies connected to your controller.

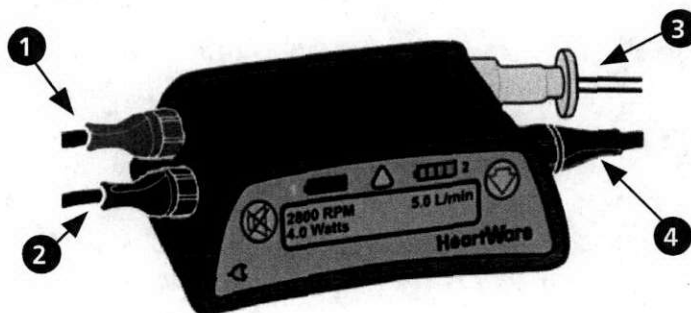


Figure 3: Controller

1. Monitor Connection
2. Power Connection
3. Driveline Connection
4. Power Connection

CAUTION: Tell your physician if you have sight or hearing problems. The controller uses words, lights and sounds to tell you how the system is operating and when to seek additional help.

6.2.1 Using the Controller

Controller Connections

There are four connectors on the controller (see Figure 3): 2 power supply connectors, 1 driveline connector, and 1 monitor connector.

- The **power supply connectors** are identical and are used to provide power to the controller. The controller should always be connected to two power sources, either 2 batteries, or 1 battery and an AC adapter or DC adapter (car adapter). To preserve battery life, use the AC adapter when you are resting or sleeping.
- The driveline is attached to a silver **driveline connector**. Never disconnect the driveline from the controller unless an emergency controller exchange is required.

WARNING! DO NOT disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

- The **monitor connector** (blue) is used by clinicians to change pump settings and to collect information about your pump. For emergency situations, you may put the alarm adapter in this connector to silence the “No Power” alarm.

Controller Display, Buttons and Indicators

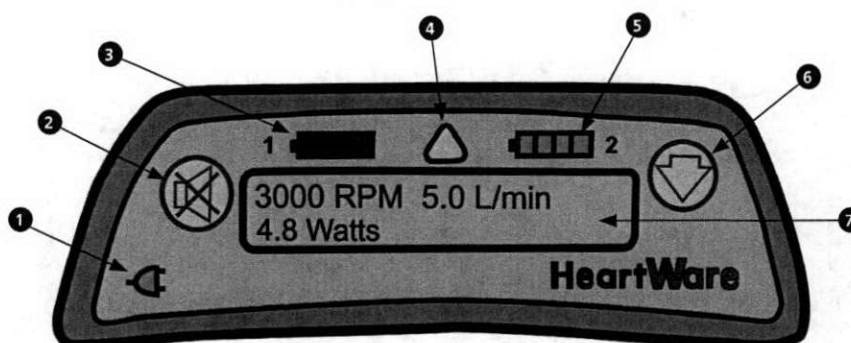
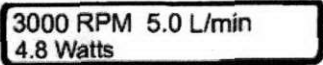
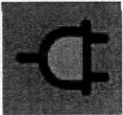
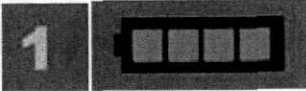
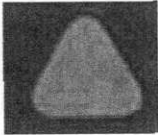
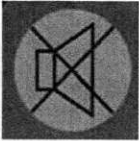
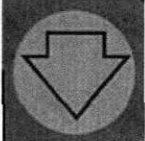
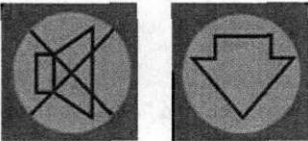


Figure 4: Controller Display with Pump Parameters:

1. AC/DC Indicator
2. Alarm Mute
3. Battery Indicator #1
4. Alarm Indicator
5. Battery Indicator #2
6. Scroll Button
7. Controller Display

| Guide to Controller Display, Buttons, and Indicators (Refer to Figure 4) | |
|---|---|
|  | <p>The CONTROLLER DISPLAY gives pump information including impeller speed (RPM), power (Watts), and blood flow (L/min). When an alarm occurs, the pump information is replaced by two lines of text that tell you what the alarm is and what to do. Section 7, Alarms, describes alarms in detail.</p> |
|  | <p>The AC/DC INDICATOR will be green if you are using the AC adapter or DC adapter to power the controller.</p> |
|  | <p>The two BATTERY INDICATORS located on the top of the controller are labeled "1" and "2". Either the "1" or "2" will be lit, depending upon which port is providing primary power. If an AC or DC adapter is connected, this will be the primary power source.</p> <p>The Battery Indicators tell you approximately how much power remains in each battery.</p> <ul style="list-style-type: none"> • 75-100% battery capacity: 4 GREEN lights • 50-74% battery capacity: 3 GREEN lights • 25-49% battery capacity: 2 YELLOW lights • Less than 24% battery capacity: 1 RED light <p>Note: If the AC adapter or DC adapter is connected to the controller, the corresponding Battery Indicator will not display lights but the corresponding "1" or "2" will be lit.</p> |
|  | <p>The ALARM INDICATOR lights when one or more alarms occur. The Alarm Indicator changes colors depending on the severity of the alarm and always displays the most severe alarm in the case of multiple alarms. The display for each alarm priority includes:</p> <ul style="list-style-type: none"> • High Alarm: Flashing Red • Medium Alarm: Flashing Yellow • Low Alarm: Solid Yellow |

| | |
|---|--|
|  | <p>The ALARM MUTE BUTTON will silence (mute) a low or medium alarm for 5 minutes or until a new alarm occurs. A high alarm cannot be silenced. Call your clinician for all medium and high alarms.</p> |
|  | <p>The SCROLL BUTTON on the right side of the controller is used to see all active alarms as well as pump information (RPM, L/min, Watts) on the Controller Display. The Scroll Button will also clear resolved medium alarms from the Controller Display and will brighten the Controller Display.</p> |
|  | <p>Simultaneously pressing and holding the ALARM MUTE Button and the SCROLL button for 5 seconds will prevent the "No Power" alarm from sounding when power is removed during a controller exchange (see Section 6.2.2, "How to Change the Controller"). Use only on a controller not connected to a pump.</p> |

Other Controller Components: Driveline Cover

The driveline cover should always cover the silver driveline connector (Figure 5) unless an emergency controller exchange is required. With proper driveline cover position you should NOT see the silver driveline connector.

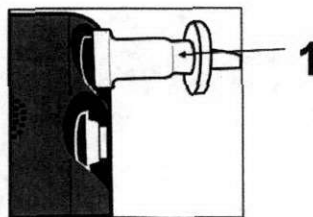


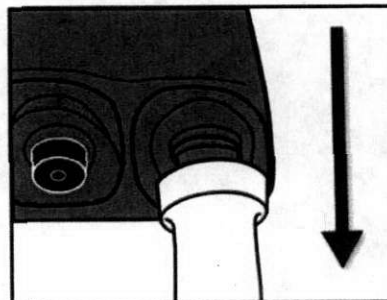
Figure 5: Driveline Cover (1) Over Connector

6.2.2 How to Change the Controller

1. Sit or lie down.
2. Place the new controller within easy reach.
3. Connect back-up power sources to the new controller.
 - Confirm that the power cables are properly locked on the controller by gently pulling on the cable near the connector.
 - A "Power Disconnect" alarm will activate if a second power source is not connected to the new controller within 20 seconds of controller power up.

- A "VAD Stopped" alarm will activate if the pump driveline is not connected to the new controller within 10 seconds. This alarm will resolve once the pump driveline is connected.

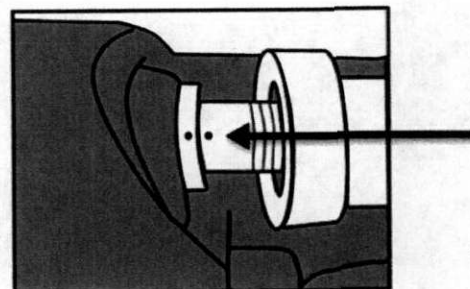
4. Pull back the white driveline cover from the original controller's silver connector.



5. Disconnect the driveline from the original controller by pulling the silver connector away from the controller. Do not disconnect by pulling on the driveline cable. A "VAD Stopped" alarm may activate. Don't panic. You can silence the alarm after you get your pump restarted. Restarting your pump is the priority.

6. Connect the driveline to the new controller (align the two red marks and push together). If the "VAD Stopped" alarm was active on the new controller, it will now resolve.

- The pump should restart. Verify that the pump is working. The RPM, L/min and Watts numbers should show on controller display. **If your pump does not restart, call for medical assistance immediately.**



7. To prevent the controller alarm from sounding after the power is removed, follow these instructions:
 - If a red alarm adapter is available, insert it into the blue connector on the original controller.
 - If no alarm adapter is available:
 - Press and hold the Alarm Mute and Scroll buttons on the original controller until a “beep” is heard, or for at least 5 seconds.
 - Release the Alarm Mute and Scroll buttons.



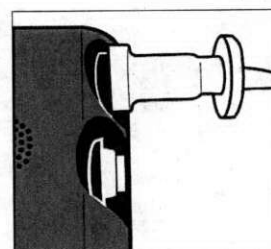
Alarm



Press and Hold the Alarm Mute and Scroll Buttons

NOTE: If the “No Power” alarm is not disabled prior to removing both power sources, the controller alarm may sound for up to 2 hours.

8. Disconnect both power sources from the original controller. The controller will be turned off and all alarms silenced.
9. Slide the white driveline cover up to cover new controller’s silver connector.



Replace Driveline Cover

10. Contact your VAD coordinator or hospital to obtain a new back-up controller.

WARNING! ALWAYS keep a spare controller and fully-charged spare batteries available at all times in case of an emergency.

WARNING! DO NOT attach the alarm adapter to a controller that is connected to a running pump. The alarm adapter silences the "No Power" alarm and should only be attached to a controller that has failed or malfunctioned and is no longer connected to a pump.

6.3 Power Sources for the HeartWare® Controller

The controller requires two power sources for safety: either two batteries (Figure 6), or one battery and an AC adapter (Figure 7) or DC adapter (Figure 8). While active, you will typically use two batteries. While relaxing or sleeping, you should use power from an electrical outlet (AC adapter) because it provides power for an unlimited period of time. Remember, the batteries must be exchanged when their charge becomes low and an extra set of fully charged batteries should always be available.



Figure 6: Battery



Figure 7: AC Adapter



Figure 8: DC Adapter

6.3.1 Connecting Power Sources

1. To connect all power supplies (battery, AC adapter or DC adapter) grasp the power cable near its connector. Leave the connector free to rotate.
2. Line up the solid white arrow on the cable connector with the white dot on the controller (Figure 9).
3. Gently push the cable into the controller. DO NOT twist the connector, but allow it to naturally lock in place. A good connection will result in an audible click.

NOTE: When pushing the connector into the controller the white arrow will shift slightly. Correct locking position: White arrow aligned with white dot on controller.

4. Confirm that the power cable is properly locked to the controller (Figure 10) by gently pulling on the cable near the connector.
5. Repeat steps above for second power source.

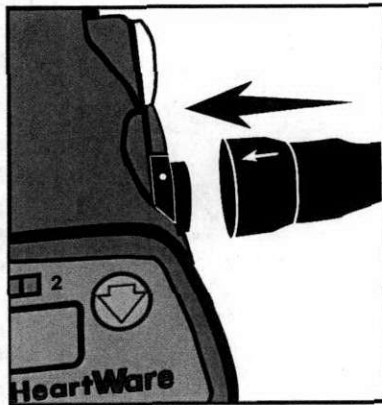


Figure 9: Connect Power Supply: Align White Arrow and White Dot



Figure 10: Correct Locking Position: White Arrow Aligned to White Dot

CAUTION: ALWAYS confirm that the power cables are properly locked to the controller by gently pulling the cable near the connector.

CAUTION: DO NOT force connectors together without proper alignment. Forcing together misaligned connectors may damage the connectors.

CAUTION: ALWAYS keep all connectors free of liquid, dust and dirt, or the HeartWare® System may not function as intended.

CAUTION: DO NOT pull, twist or kink the driveline or power cables, especially while sitting, getting out of bed, adjusting controller or power sources, or when using the shower bag.

6.3.2 Disconnecting Power Sources

1. Turn the connector counterclockwise until it stops.
2. Pull the connector straight out from the controller.
3. If another power source is not connected within 20 seconds, the "Power Disconnect" message will be displayed on the Controller Display and an alarm will sound.

NOTE: The alarm will automatically clear when another power source is connected to the controller.

6.3.3 Changing Power Sources

Changing from two batteries to a battery and AC/DC adapter:

1. Plug the AC adapter into a grounded electrical outlet or the DC adapter into a power port found in most cars.
2. Disconnect the battery with the least remaining charge.
3. Connect AC or DC adapter per Section 6.3.1, Connecting Power Sources.

Proper connection is verified when the AC/DC Indicator on the controller turns green and the corresponding Battery Indicator turns off. If the AC/DC Indicator doesn't turn green, the controller is using battery power and the "Power Disconnect" alarm will sound.

WARNING! DO NOT plug the AC adapter into an electrical outlet that is not properly grounded or you may receive a serious electrical shock.

CAUTION: ALWAYS check to be sure the DC adapter works in your motor vehicle. The DC adapter is for use in motor vehicles only and may not fit all motor vehicles.

CAUTION: Use only HeartWare-supplied power adapters with the HeartWare® System.

Changing from an AC/DC adapter and battery to two batteries:

Before switching from AC or DC power to battery power, make sure that a fully charged battery is available. Connect the fully charged battery after disconnecting the AC or DC adapter.

6.3.4 Using Battery Power

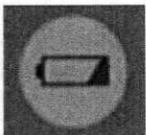
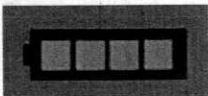
Each fully charged battery provides approximately 4 to 6 hours of use for normal activities such as reading or watching TV. The battery may last for less time as your activity level increases. However, if any battery provides less than 2 hours of support, it should be replaced.











Figure 11: Battery

1. Battery Capacity Display

2. Test Button

| Battery Buttons and Indicators (refer to Figure 11) | |
|--|--|
|  | Pressing the TEST BUTTON will light up the Battery Capacity Display. |
|  | The BATTERY CAPACITY DISPLAY will tell you how much power remains in the battery. |

The Battery Capacity Display (Figure 11) on the battery is *similar* to the Battery Indicator on the controller (see Section 6.2.1, “Using the Controller”), except that only green lights are used on the battery. For example, at 25-49% capacity, 2 green lights will be displayed on the battery while 2 yellow lights will be displayed on the controller (see chart below).

| Battery Capacity | Battery Capacity Display on BATTERY | Battery Indicator on CONTROLLER |
|------------------|--|---|
| 75-100% | 4 GREEN lights  | 4 GREEN lights  |
| 50-74% | 3 GREEN lights  | 3 GREEN lights  |
| 25-49% | 2 GREEN lights  | 2 YELLOW lights  |
| less than 24% | 1 GREEN light  | 1 RED light  |

When one battery is depleted to less than 25% capacity, the controller will automatically switch to the other battery. An intermittent “beep” will sound, the Alarm Indicator (\triangle) will be yellow, and a message will be displayed to replace the depleted battery (Figure 12). If the battery is **NOT** changed within 5 minutes, the alarm volume will escalate until the battery is exchanged with a fully charged battery.

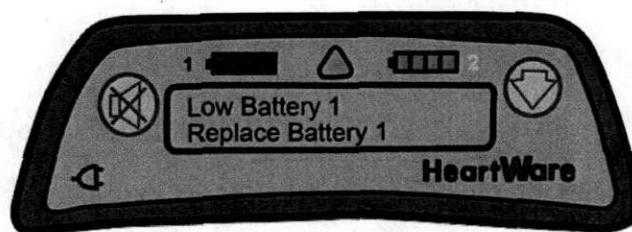


Figure 12: Controller Display with a Low Battery Alarm

When a depleted battery is not exchanged and there are only a few minutes of battery time remaining in both batteries, a high priority alarm will sound, the Alarm Indicator will be flashing RED and the message on the Controller Display will read “Critical Battery.” If this happens, there are only a few minutes of power remaining before the pump stops. The batteries should be exchanged immediately.

6.3.5 Changing a Battery

Make sure there is a fully-charged battery available to replace the depleted battery. Disconnect the depleted battery and replace it with the fully-charged battery. (See Section 6.3.1 and Section 6.3.2 for details on how to connect and disconnect power sources.) After a depleted battery is disconnected, the “Low Battery” alarm will resolve, as the controller will automatically switch to the second power source. If the second power source is not connected within 20 seconds, the “Power Disconnect” message will be displayed on the Controller Display and an alarm will sound. The alarm will automatically clear when the second power source is connected. When the battery is connected correctly, the Battery Indicator on the controller should light.

6.3.6 Care of Batteries

Your batteries include many features to make them safe and dependable. However, you must care for them properly.

Things to do:

1. To preserve battery life, batteries should be stored at room temperature. Protect batteries from extreme high and low temperatures.
2. Use all of your batteries. There is a serial number on each battery so you can rotate batteries.
3. Don't leave home without extra, fully charged batteries.
4. Protect the battery connector from moisture, dirt and metal at all times.
5. Handle connectors so as to avoid touching the inside.
6. Batteries should be left in the battery charger and charging when not in use.

CAUTION: ALWAYS recharge completely depleted batteries within 24 hours to avoid permanent battery damage.

Things NOT to do:

1. Avoid leaving the batteries exposed to extreme heat, especially in direct sunlight or in a closed car in the sun. The temperature can easily reach 60-65°C (140° to 150°F) which can damage the batteries.
2. DO NOT drop the batteries or let them hit hard objects.
3. DO NOT let the batteries get wet.
4. DO NOT kink or twist the battery cables.
5. DO NOT force connections to the controller or battery charger.

6.4 HeartWare® Battery Charger

The battery charger is used to charge up to 4 batteries at a time. It takes about 4 to 5 hours to fully charge a battery. The battery charger (Figure 13) must be plugged into an AC power outlet to charge batteries. The power indicator is green when the battery charger is properly connected to electrical power. Each battery slides into a slot and the battery is connected to the battery charger. It is safe to leave the battery connected to the charger when not in use.

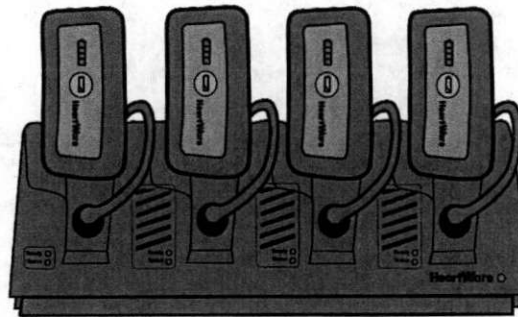


Figure 13: Battery Charger

When a battery is connected, the battery charger checks the battery and begins charging. The battery charger power light is located next to "HeartWare" (Figure 14); when lit, it means the battery charger is connected to AC power (plugged into a wall outlet). Each battery charging slot has two lights that tell you the status of the battery. A green light next to "Ready" means the battery is fully charged. The light next to "Status" may mean different things, depending upon the color. The table below describes the lights that appear next to "Status."

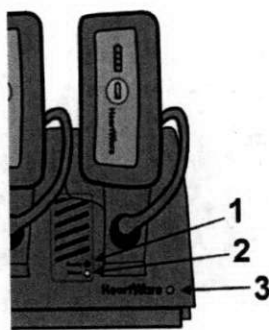


Figure 14: Indicator Lights on Battery Charger:

1. Ready Light
2. Status Light
3. Battery Charger Power Light

| Battery Charger "Status" Light | What it Means |
|--------------------------------|--|
| Yellow | Battery being charged; NOT ready for use. |
| Flashing Yellow | Battery not charging. Check battery connections. If connections are intact, switch to another battery slot. If problem persists, return battery to Clinician. |
| | Battery too cold or too hot; waiting to charge. |
| | Defective battery. Do NOT use. Mark battery and return to Clinician. |

6.4.1 Connecting Batteries to the Battery Charger

The battery connects to the battery charger the same way it connects to the controller.

1. Grasp the cable of the battery near the connector, leaving the connector free to rotate.
2. Line up the solid white arrow on the connector with the white dot on the battery charger.
3. Gently push the cable into the battery charger until it locks in place.

6.4.2 Disconnecting Batteries from the Battery Charger

Disconnect the battery by turning the connector counterclockwise until it stops, then pull the connector straight out from the battery charger.

CAUTION: NEVER use other battery chargers to charge HeartWare® batteries. Other battery chargers may damage the batteries.

CAUTION: ALWAYS wait until the "Ready" light turns on to disconnect the battery from the battery charger. If this is not followed over consecutive charging cycles, the Battery Capacity Display will not function properly and may convey misleading battery capacity.

7 ALARMS

Alarms tell you about the pump, controller, connections, and power supplies (batteries, AC adapter, DC adapter). Alarm conditions are classified as high, medium or low. Each of these alarms has a 1) unique sound, 2) visual display (flashing RED, flashing YELLOW or YELLOW) and 3) a message. **When an alarm occurs, two lines of text appear in the Controller Display. The first line tells you what the alarm is and the second line tells you what to do.** When an alarm is resolved, there is no longer an alarm sound or a light displayed in the Alarm Indicator (△). A high alarm is very serious. If you have a high alarm, you need to take immediate action. Please call your physician, nurse or VAD coordinator for any high alarm or medium alarm. A low alarm reminds you to exchange a low battery with a fully charged battery or to reconnect to a power supply (battery or AC/DC adapter). In addition to the high, medium and low alarms, there is a "No Power" alarm that sounds if both power sources are removed from the controller. (See "Quick Reference Guide for Alarms" in the front of this manual, for a complete list of high, medium and low alarms.)

WARNING! ALWAYS replace a controller with a blank display or and/or no audible alarms.



7.1 No Power Alarm

When both power supplies (batteries, AC adapter, DC adapter) are removed, there will be NO message on the Controller Display. A loud continuous alarm will sound but the Alarm Indicator WILL NOT light. Your pump has stopped. You need to connect two power supplies immediately. If this does not resolve the alarm, immediately replace the controller with the back-up controller.

WARNING! NEVER disconnect both power sources (batteries, AC adapter, DC adapter) at the same time since this will stop the pump and activate the No Power alarm. At least one power source must be connected at all times.

7.2 High Alarms

A high alarm is the loudest alarm; the Alarm Indicator on the controller is flashing RED and the text message demands immediate action for VAD (pump) stoppage, controller failure or limited power to run the pump. High alarms include the following:

| Alarm (Line 1 on controller) | Action (Line 2 on controller)^ | Meaning | Alarm Indicator  | Alarm Sound |
|------------------------------------|--------------------------------------|---|---|----------------------------------|
| VAD Stopped | Connect Driveline | Driveline disconnected or connector malfunction/ broken |  | Loud Unable to mute alarm |
| VAD Stopped | Change Controller | Controller failure | | |
| Controller Failed | Change Controller | Controller failure | | |
| Critical Battery 1 | Replace Battery 1 | Limited battery 1 and battery 2 time remaining | | |
| Critical Battery 2 | Replace Battery 2 | Limited battery 2 and battery 1 time remaining | | |

^ Immediate action required, and then call your physician, nurse or VAD coordinator

ALL high alarms will display a message on the Controller Display and the Alarm Indicator will flash red. The VAD will stop if the driveline is disconnected or if the controller fails. For a "VAD Stopped" alarm, the text message will tell you whether to connect the driveline or change the controller, as both of these situations may trigger this alarm.

The "Controller Failed" alarm indicates a potential controller failure; the controller should be exchanged with the back-up controller.

WARNING! ALWAYS switch to the backup controller if there is a "Controller Failed" alarm.

The "Critical Battery" alarm is displayed when both batteries only have a few minutes of battery time remaining to power your pump. Replace the depleted batteries with fully charged batteries or use your AC adapter or DC adapter.


7.3 Medium Alarms

The medium alarm starts at a low volume and gets louder over the next minute, unless the Alarm Mute button is pressed. A medium alarm is indicated by a flashing YELLOW Alarm Indicator, and the text message tells you to call medical personnel. Please call your doctor or nurse immediately to receive instructions.

| Alarm (Line 1 on controller) | Action (Line 2 on controller) | Meaning | Alarm Indicator △ | Alarm Sound |
|---------------------------------|----------------------------------|--|----------------------|--|
| High Watts | Call* | A change in the status of your VAD is detected | Flashing YELLOW | Gradual increase in volume over the first minute if alarm not muted. |
| Electrical Fault | | | | |
| Low Flow | | | | |
| Suction | | | | |
| Controller Fault^ | Call* | Possible controller malfunction | | Alarm gets louder after 5 minutes if alarm not muted. |
| Controller Fault^ | Call: ALARMS OFF* | | | Able to mute alarm for 5 minutes by pressing Alarm Mute Button. |

^ Controller Fault indicates a possible controller malfunction, call your clinician for appropriate action. The controller may need to be replaced with the back-up controller.

* Call your doctor, nurse or VAD coordinator immediately.

When a medium alarm resolves there is no alarm sound or light displayed in the Alarm Indicator. However, the message on the Controller Display will remain until you clear this message by pressing the Scroll button . A new alarm will also clear a resolved medium alarm from the Controller Display.

7.4 Low Alarms

A low alarm is indicated by a solid YELLOW Alarm Indicator. The message tells you to replace a low battery or reconnect to a power source (battery, AC adapter or DC adapter).

| Alarm (Line 1 on controller) | Action (Line 2 on controller) | Meaning | Alarm Indicator △ | Alarm Sound |
|---------------------------------|----------------------------------|--|----------------------|--|
| Low Battery 1 | Replace Battery 1 | Battery 1 is low | YELLOW | Alarm gets louder after 5 minutes and even louder after 10 minutes, if alarm not muted. Able to mute alarm for 5 minutes by pressing Alarm Mute Button. |
| Low Battery 2 | Replace Battery 2 | Battery 2 is low | | |
| Power Disconnect | Reconnect Power 1 | Power source 1 disconnected or defective | | |
| Power Disconnect | Reconnect Power 2 | Power source 2 disconnected or defective | | |

7.5 Multiple Alarms

You may have more than one alarm condition at the same time. For multiple alarms, the Alarm Indicator (△) will display the most severe alarm and the alarm will sound the most severe alarm. As mentioned previously, when an alarm occurs, two lines of words appear on the Controller Display. The first line tells you what the alarm is, and the second line tells you what to do. An arrow (↓) is displayed on the right side of the alarm if there is more than one alarm (Figure 15).

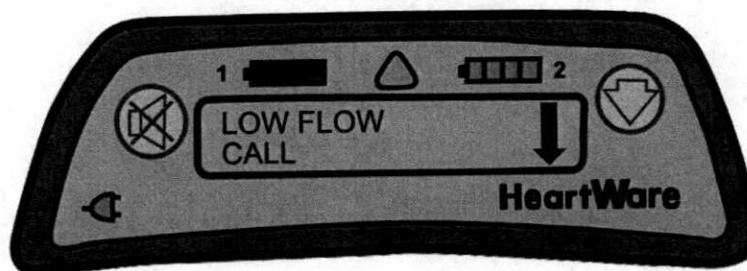

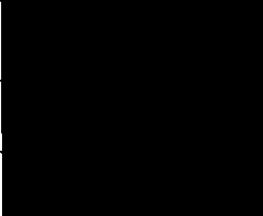




Figure 15: Controller with Multiple Alarms (Note Arrow in Controller Display)

Alarm Indicator and Alarm Sound for Multiple Alarms

| Multiple Alarm Condition | Alarm Indicator  | Alarm Sound |
|---------------------------------|---|---|
| 2 or More High Alarms |  | Loud, continuous, unable to mute |
| High and Medium Alarms | | Loud, continuous, unable to mute |
| High and Low Alarms | | Loud, continuous, unable to mute |
| 2 or More Medium Alarms | Flashing YELLOW | Gradual increase in volume if alarm NOT muted |
| Medium and Low Alarms | Flashing YELLOW | Gradual increase in volume if alarm NOT muted |
| 2 or More Low Alarms | YELLOW | Gradual increase in volume if alarm NOT muted |

Use the Scroll button  to see all alarm conditions. Press the Scroll button each time you want to advance to the next alarm or to the pump parameters (L/min, RPM and Watts). If the Scroll button is not touched for 1 minute, the controller automatically displays the most severe alarm on the Controller Display. Also, if a new alarm occurs, the Controller Display will show you the new alarm. Remember, if an arrow is displayed on the right side of the alarm message; use the Scroll button to see all alarms.

7.6 How to Silence (Mute) Alarms

High alarms CANNOT be silenced. However, medium and low alarms can be silenced for 5 minutes by pressing the Alarm Mute button . The alarm will sound again if a new alarm condition occurs or five minutes has passed. The low and medium alarm sound will increase to the next highest alarm volume level if the alarm condition is not resolved or is not muted within 5 minutes.

WARNING! ALWAYS investigate, and if possible, correct the cause of any alarm. Silencing an alarm does not resolve the alarm condition.

CAUTION: ALWAYS call your clinician for appropriate action if there is a "Controller Fault" high alarm. The controller may need to be replaced with the back-up controller.

8 EQUIPMENT CARE AND MAINTENANCE

8.1 How Long HeartWare® Equipment Should Last

The HeartWare® System components were designed and tested to function without failing for the following periods:

- HVAD® Pump at least two years.
- The controller is expected to function for at least one year.
- The battery charger is expected to function for at least one year.
- The battery is expected to function through a minimum of 500 charge and discharge cycles; this will provide patient support for at least one year.

8.2 General Care

The HeartWare® Ventricular Assist System is made of durable materials that will need occasional cleaning. The following steps should be used to clean the equipment:

1. Use a clean, soft cloth when cleaning the system (controller, batteries, battery charger).
2. Gently clean the equipment. Avoid hard rubbing.

WARNING! DO NOT use any components other than those supplied by HeartWare with the HeartWare® System, as this may affect HeartWare® System operation.

WARNING! DO NOT disconnect the driveline or power sources from the controller while cleaning it or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

WARNING! DO NOT drop the controller or other equipment. Dropping the controller could cause sudden stoppage of the pump. Dropped equipment should be reported and inspected.

WARNING! Damaged equipment should be reported to your VAD coordinator and inspected.

CAUTION: DO NOT attempt to repair or service any components of the HeartWare® System. If service is required, contact your physician, nurse or VAD coordinator.

CAUTION: ALWAYS keep all connectors free of liquid, dust and dirt, or the HeartWare® System may not function as intended.

8.3 Controller

Once a week: Inspect the power connectors and connector pins on the controller for dirt or grime. This inspection can be done when you are changing power sources. Check the controller power

connectors one at a time. DO NOT disconnect both power sources at the same time – your pump will stop. DO NOT disconnect the driveline to examine its connector. The only time the driveline connector should be inspected is during a controller exchange. DO NOT attempt to clean the controller connectors. If any dirt is found, report the condition to your VAD coordinator.

8.4 Batteries

Once a week: Inspect batteries for physical damage, including the battery cable and connectors. DO NOT use batteries that appear damaged. Damaged batteries must be replaced.

Periodically or as needed:

- Note how long your batteries last. If a battery lasts less than 2 hours after being fully charged, contact your VAD coordinator for a replacement.
- Clean the exterior surfaces of batteries using a clean cloth. A damp cloth may be used but a wet cloth should not be used.

Disposal: Consult your VAD coordinator, nurse or physician.

CAUTION: DO NOT place batteries in water or liquid.

CAUTION: DO NOT expose batteries to temperatures less than 32°F (0°C) or greater than 113°F (45°C) or the battery may run the pump for less time than usual. To preserve battery life, batteries should be stored at room temperature.

CAUTION: DO NOT expose batteries to excessive shock or vibration.

CAUTION: DO NOT disassemble, crush, or puncture a battery.

CAUTION: DO NOT short the external contacts on a battery.

CAUTION: ALWAYS keep batteries away from children. Children may be harmed by damaged batteries or components.

CAUTION: DO NOT use a damaged battery.

CAUTION: DO NOT touch the fluid if a battery pack is leaking fluid. Dispose of a leaking battery pack. In case of eye contact with fluid, DO NOT rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention.

CAUTION: DO NOT dispose of a battery in fire or water. Dispose of batteries according to federal, state, and local regulations.

8.5 Battery Charger

Once a week:

- Inspect the battery charger for signs of physical damage, such as dents, chips, or cracks. DO NOT use the charger if it shows signs of damage. Obtain a replacement from your VAD coordinator.

- Inspect the power cord that connects the battery charger to a wall electrical outlet. Make sure the cord is not kinked, split, cut, cracked, or frayed. DO NOT use the cord if it shows signs of damage. Obtain a replacement power cord from your VAD coordinator.

Periodically or as needed: To clean the battery charger, remove the batteries and unplug the charger from the electrical outlet. Clean the exterior surface of the charger using a clean, dry cloth. DO NOT place the charger in water or liquid.

WARNING! NEVER clean the battery charger with the power on, as this may lead to an electrical shock.

9 ACTIVITIES OF DAILY LIVING

Talk to your physician about your usual activities as well as any changes in your daily routine. Your HeartWare® System is designed to help you stay active. However, each person is different and your physician can give you the best advice. Anytime you have questions or concerns, talk to your physician, nurse or VAD coordinator.

CAUTION: DO NOT play contact sports. You may start bleeding or could damage your equipment.

WARNING! ALWAYS check the controller display for any information regarding an alarm when using loud machinery or in the vicinity of loud noises since under these conditions, the controller and battery alarms may not be audible.

WARNING! DO NOT become pregnant while you have the HeartWare® System. If you are a woman of childbearing age, use birth control if you are sexually active. Blood thinners (which most LVAS patients receive) have been associated with birth defects. If you do become pregnant, tell your physician and hospital contact person immediately.

WARNING! DO NOT have a magnetic resonance imaging (MRI) procedure while implanted with the HeartWare® System. Doing so could harm you or could cause the pump to stop.

WARNING! Keep mobile phones at least 20 inches (50 centimeters) away from the controller, as mobile phones may interfere with controller operation.

WARNING! DO NOT undergo procedures requiring high power electrical treatment (e.g. application of diathermy) while the pump is implanted.

WARNING! AVOID exposure to therapeutic levels of ultrasound energy. Consult your physician before having lithotripsy procedures to treat kidney stones or any treatments involving high intensity ultrasound. The implanted device may inadvertently concentrate the ultrasound field and cause harm.

WARNING! AVOID therapeutic ionizing radiation. Consult your physician before having any nuclear medicine procedures or radiation therapy for cancer. Radiation may damage the device and may not be immediately detectable.

9.1 Driveline Exit Site Care

Proper care of your skin around the driveline exit site is very important to prevent infection in this area. Prior to leaving the hospital, your nurse should explain and demonstrate proper care of the exit site. One of the most important measures you can take to prevent exit site infections is to protect the driveline from excessive movement. Take care not to pull on the driveline or get it caught on objects where the result may be sudden pulling or yanking.

The dressing around your exit site should be changed according to your doctor's instructions. Always thoroughly wash your hands with soap and water prior to any dressing change. Always use sterile technique with every dressing change. General guidelines include:

1. Obtain all necessary materials
2. Wash your hands thoroughly
3. Remove dressing
4. Observe exit site for redness, swelling or drainage
5. Open new dressings
6. Use sterile gloves
7. Cleanse the exit site with saline or other agent (start close to the driveline and then move away)
8. Apply sterile dressings
9. Tuck any excess driveline length under an abdominal binder or dressing or keep it secured close to the body by clothing

CAUTION: DO NOT pull, kink or twist the driveline or the power cables. Special care should be taken not to twist the driveline while sitting, getting out of bed, adjusting controller or power sources, or when using the shower bag.

CAUTION: ALWAYS keep extra driveline length tucked under clothing or secured with an abdominal binder or dressing. Do not let any portion of driveline hang freely where it might get caught on external items such as doorknobs or the corners of furniture.

CAUTION: ALWAYS notify your physician promptly if there is drainage, swelling or reddened skin around the driveline exit site, these may indicate an infection.

CAUTION: DO NOT use prophylactic topical antibiotic ointments such as silver sulfadiazine, betadine, or polymyxin-neomycin-bacitracin ointment. These ointments can injure the tissue adjacent to the exit site.

CAUTION: ALWAYS examine the driveline for evidence of tears, punctures or breakdown of any of the material during exit site dressing changes. Report any damage to your physician, nurse or VAD coordinator.

CAUTION: ALWAYS notify your physician promptly if you notice blood or fluid in the driveline. The section of the driveline inside your body may have been damaged during HVAD® Pump implantation or during another operation. The driveline has built in features that minimize the effect of blood or fluid entering it, so the HVAD® Pump should continue to operate normally. However, your physician should examine the driveline to fully evaluate the situation.

9.2 Showering

Your doctor will let you wash your incisions after your wounds have healed. When you wash, the controller, batteries and connectors must be protected from water and you should take care so that water doesn't run down the driveline onto the controller. The exit site should also be kept as dry as possible. Keeping the exit site dry helps avoid infections.

Your doctor will decide if it is safe for you to shower. If your doctor gives you permission to shower, you must use the HeartWare® Shower Bag to protect the controller and batteries. For instructions on shower bag use, please see Section 10.3 "HeartWare® Shower Bag".

WARNING! DO NOT shower until your physician tells you it is safe to do so. If you receive permission to shower, you must use the HeartWare® Shower Bag. If your hearing is impaired and/or you cannot hear the controller alarms without the use of a hearing aid, make sure your caregiver will be close by to hear alarms.

WARNING! DO NOT plug the controller into an AC wall outlet during showers; it should be connected to two batteries.

WARNING! DO NOT take a bath or swim.

WARNING! DO NOT submerge any HeartWare® System component in water.

9.3 Medications

Talk with your doctor about your medications. Get an explanation of the purpose of each medication that your doctor prescribes for you. Write down the medication and how often you need to take it and ask your doctor to check the list to make sure it is correct. Talk with your doctor about what you should do if you accidentally forget to take your medicine. Discuss what to do for each medicine because it may be different for each one. You may also want to make a list of medications that you should not take. Some non-prescription medications and natural supplements may react with your prescribed medications.

You are probably taking medication (anticoagulation) to thin your blood and reduce the risk of clot formation in your blood or pump. It is very important that you take this medication as prescribed and that you have your blood checked frequently to be sure that you are receiving a dose that is not too high (blood too thin) or too low (blood too thick).

You may notice bleeding as a result of your medication. If you are unsure whether the bleeding represents a problem, it is best to call your doctor or nurse.

NOTE: You should always remain on your anticoagulation dose schedule as written or as told to you by your doctor or nurse.

10 EQUIPMENT NEEDED FOR HOME USE

At the time of discharge from the hospital, be certain that all of the following equipment and accessories are available and have been checked for proper function.

10.1 Home Discharge Equipment Requirements

- 1 Patient Manual
- 2 Controllers with AC adapters (1 set is for back-up) and alarm adapters
- 1 Driveline cover
- 1 DC adapter
- 4 - 6 Batteries
- 1 Battery charger
- 1 Patient Pack
- 1 Shower bag

10.2 Patient Packs

The HeartWare® Patient Pack is used to safely secure, store and carry the controller and batteries. A viewing window allows you to see the controller display. The patient pack can be used in or out of the hospital, when resting, sleeping or ambulating. One controller and two batteries fit into the pack.

Patient Pack Care Instructions:

Patient Packs can be washed by hand using a mild detergent and cold water, or machine washed using the delicate cycle. DO NOT use bleach. Allow the pack to air dry. DO NOT use a clothes dryer to dry the waist pack. Make sure that waist pack is completely dry before using, and inspect it for damage or wear before each use.

10.3 HeartWare® Shower Bag

NOTE: Please see Section 10.3.1 "Getting Ready to Shower", for additional instructions and warnings related to showering with your HeartWare® System.

The HeartWare® Shower Bag provides the ability to comfortably and securely shower with your HeartWare® Ventricular Assist System. The shower bag is water resistant, not water proof, and protects the controller and batteries from direct water spray and moisture. A small amount of water accumulation in the bag is acceptable and will not affect proper function of the system. The shower bag permits one (1) controller and two (2) batteries to be placed into a single compartment.

The cover of the bag has a zipper closure that allows the driveline to exit on the right side of the bag. An adjustable shoulder strap is used to wear the bag during showering. When showering, always use two batteries as the controller power sources. DO NOT use the HeartWare® Controller AC Adapter as one of the controller power sources. Always use the HeartWare® Shower Bag to protect the controller and batteries when showering.

Recommendations:

- Keep the driveline exit site covered and as dry as possible while showering.
- Try not to pull or move the driveline. Pulling or moving the driveline could injure an already healed exit site. DO NOT kink or bend the driveline.
- Be careful not to catch the driveline in the zipper when closing the shower bag.
- Prior to showering, make sure both batteries are completely charged.
- If you are hearing impaired, your ability to hear alarms will be reduced. If any alarm is heard during showering, immediately turn off the shower and address the alarm condition. If you require hearing aids, make sure someone will be close by to hear alarms.
- The shower stall floor should be made of a non-slip surface or have a textured rubber mat.
- The shower stall should have a handrail and shower chair.

10.3.1 Getting Ready to Shower

Please follow these steps to use the shower bag:

1. Unzip and open the shower bag. Inspect the shower bag for rips or tears and be sure the inside of the bag is dry. If the integrity of the bag is compromised in any way, do not use the

bag and do not proceed to shower. If needed, contact your VAD coordinator to get a replacement.

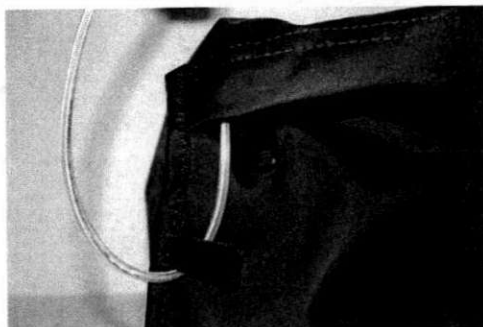
2. Remove the controller and two batteries from the patient pack and carefully place them inside the inner pouch of shower bag. Pull the drawstring closed.



3. With the shower bag opening away from you, position the driveline towards the farthest right corner of the zipper. You will see an area of the zipper that has no teeth. Place the driveline between the upper and lower nylon guards prior to zipping the cover shut. Fold the flap down over the zipper.



4. Guide the portion of the driveline that exits the bag between the two Velcro strips on the side of the bag; firmly fasten the two strips around the driveline. The driveline will form a "U" shape as it exits the bag, thus minimizing the likelihood that water will drain from the driveline into the bag.



5. Place the shower bag strap over your head and across your shoulder so it is hanging at your side.



NOTE: The strap is adjustable. Adjust the strap so the bag does not pull on the driveline while showering. There should be some slack in the driveline so that the flap is completely folded over the zipper.

Keep the exit site as dry as possible while you shower. Proper hand washing and a dry exit site will help reduce the risk of infection. Your VAD coordinator will give you suggestions to maintain a dry exit site.

10.3.2 After Showering

6. Set the shower bag on a flat, stable surface and dry the bag, controller, and batteries, using a clean towel.
7. Transfer the controller and batteries to the patient pack.
8. Change the driveline exit site dressing using your normal procedure. If the area around the exit site is wet, dry off with a sterile gauze bandage before applying the new dressing.
9. Allow the shower bag to drip dry before using it again.

10.3.3 Caring for Your HeartWare® Shower Bag

Keeping your shower bag clean will help ensure it works properly and lasts longer. It can be washed by hand using a mild detergent and cold water. Once the bag has been washed, allow it to drip dry. Never heat the shower bag to dry it or place it in an electric or gas heated clothes dryer. Make sure your shower bag is completely dry before taking the next shower. Inspect your shower bag for damage or wear before each use. If you have problems or questions about your HeartWare® Shower Bag, your VAD coordinator can assist you.

11 HANDLING AN EMERGENCY

A back-up controller and charged batteries must be available at all times. The controller should be exchanged if it fails. A controller failure is a high alarm and the Controller Display will tell you to "Change Controller" (see Section 6.2.2, "How to Change the Controller"). Call your physician immediately if you notice a sudden change in how your pump works, feels or sounds (even if there is no alarm). If there is an emergency such as an urgent or life-threatening problem, call your local emergency medical services and then your physician, if possible.

Contact your physician for any of the following conditions:

- Numbness, tingling or weakness in any limb
- Blurred vision or speech problems
- Shortness of breath or dizziness
- Any pain, including chest pain, unrelieved headache
- Fever (take your temperature daily)
- Any redness, swelling or drainage around the driveline exit site
- Unusual bleeding or bruising
- Unusually dark urine
- Any condition where you feel "unwell"
- High and medium controller alarms

Call Emergency Medical Services (EMS) for any of the following conditions:

- Seizure or convulsion
- Loss of consciousness
- Awake but unresponsive
- Sudden fall or collapse
- Inability to talk or move body parts
- Heart stops
- VAD stops

12 TRAVELING AND TRANSPORT

As you resume activities of daily living, you may wish to travel away from home. Prior to making travel plans, talk with your physician to make sure it is safe for you to travel. Once you are approved for travel, your physician or VAD coordinator will work with you to ensure you are prepared for traveling safely. Always remember to take all prescribed medication with you and to make sure you have emergency contact information.

When you travel, please make sure you have the following:

- Back-up controller
- Fully-charged, spare batteries
- Battery charger
- Controller AC adapter
- Controller DC adapter

Equipment should be kept with you at all times for safety and security. If traveling by air, carry equipment with you on board the aircraft. During the flight, you should power the controller with two batteries or with one battery and an AC adapter.

NOTES

- Store and operate all equipment within the recommended temperature conditions listed in the WARNINGS and PRECAUTIONS section of this manual.
- Avoid passing through security screening equipment, as this may affect your VAD. Instead, request to be hand screened with special care given to the driveline exit site.
- If you are traveling on a long haul flight, talk with your clinician about whether you should purchase extra batteries.
- If traveling internationally, talk with your clinician about purchasing international power cords for use with your equipment

WARNING! AVOID areas with high magnetic forces such as theft detection devices or airport security systems, as these may affect HeartWare® Systems operation.

In case of emergency, it is safe for you to be transported by ground or air to the implanting facility or nearest hospital.

13 ADDITIONAL INFORMATION ABOUT HEART FAILURE

Additional information about heart failure can be found at:

- www.HeartWare.com
- <http://www.nhlbi.nih.gov/health/health-topics/topics/hf/>
- <http://emedicine.medscape.com/article/163062-overview>
- http://en.wikipedia.org/wiki/Heart_failure

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HeartWare, Inc.
14000 NW 57th Court
Miami Lakes, FL 33014 USA
www.heartware.com

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IFU00184 Rev03 11/12